

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
1	BAE SYSTEMS		All	Subjective assessment, no generation of Human Error Probabilities, no objective assessment of HF or mention of integrating into subsystem analyses (e.g. HRA, FMEA).		Requested	Not accepted	The HF process and associated assessment are by nature subjective, and it was not the intent of the CM to provide Human Error Probabilities.
2	BAE SYSTEMS		All	No mention of the Human Factors specialists to be mandated to control this process.		Requested	Noted	The CM invites the Applicant to define a process. The Human Factors specialists has to be involved in this process. The CM states that “The following activities are meant to be run by a multidisciplinary team consisting of test pilots, HF specialists, safety specialists and panel experts.”
3	BAE SYSTEMS		All	A worked example would have been useful		Requested	Noted	The CM are generally not providing worked examples.
4	KLM Engineering and Maintenance			Would it be beneficial to address distinguishable specific OEM related Human Factors as part of their specific cockpit philosophy? For example, system failures and assumptions can be different in Airbus aircraft as opposed to Boeing aircraft.			Noted	It is acknowledged that the cockpit philosophy of the different OEM can be different. This may lead to different assumptions. The CM has been written in such a way that it can apply to all OEM independently of the design philosophy.
5	KLM Engineering and Maintenance			A major change into a system, if causing an appreciable HF effect to FHA, would require a detailed Human Factors description and philosophy of that system before the modification, in order to prevent oversight of effects as a result of that modification. Questionable might be, to what extend this original Human Factors description can be acquired from the OEM, or reversed engineered. Added to the above, the approach for compliance demonstration can be significantly different in case of a new system compared with an existing (e.g. flight critical) system. The last one, probably requiring more detailed analysis, as this falls within TC-ed (critical) functionalities.			Noted	This comment is also valid for all other assumptions made as part of the initial design. The STC applicant has to ensure that the proposed modification does not invalidate the initial assumptions.

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6	AIA’s Civil Aviation Cybersecurity Subcommittee		All	<p>This Certification Memorandum provides useful guidance for considering human factors in safety assessments. With the Entry Into Force of the information security rules – including CS 25.1319 – information security risk assessments need to be performed in support of or complementary to safety assessments. Threat Conditions may be revealed by security analysis which feed failure conditions defined in the safety analysis. As with other failure conditions, these events may require interactions with flight crew and maintenance personnel through various flight deck effects and/or dependencies on crew actions and responses.</p> <p>AIA has been working with ALPA to further understand and discuss human factors in relation to aviation information security. A report will be issued in approximately 1 month.</p> <p>AIA would suggest EASA considers amending the proposed Human Factors Certification Memorandum to include consideration of human factors with information security (i.e. reference CS 25.1319). This additional guidance could either be in the initial revision or an update can be planned to take into account the AIA report and other materials.</p>			Not accepted	EASA will review the report when available. The initial scope of the CM covers HF assumptions from the Safety assessment process. It is not planned to extend to consider security at this stage.
7	Garmin		General	If the Certification Memorandum (CM) is being written due to deficiencies in the current guidance material, is the plan to incorporate the contents of the published CM into future revisions of the guidance material so the content is available in the appropriate document?	Request that the CM contain a clear statement about whether there is intent to revise the referenced AMC documents.	Requested	Noted	The content of the Cert Memo is mainly based on an EASA generic CRI/CAI which was raised on several certification and validation projects. The intend to publish it was to make the content visible and transparent and benefit from the wider experience from the community to improve the clarify the content. It is currently not planned at short term to initiate a rulemaking task to introduce the content of this CM into an EASA AMC.

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8	HeliOffshore			<p>Additional Reference Materials - In response to the abovementioned P-NPA 25.310 Human Centred Design research commissioned by the UK CAA and undertaken by Airbus considered how error might be incorporated into the SSA. It suggested mirroring the Failure Mode and Effect Analysis using a so-called Human Error Mode and Effect Analysis. This was subsequently applied by Airbus and has been adapted for use in helicopter design by HeliOffshore in a process called Human Hazard Analysis (further detail can be found here https://www.aerosociety.com/news/designing-out-human-error/)</p> <p>In relation to the consideration of maintenance error, a detailed analysis of relevant EASA rule-making has recently been undertaken by a working group of the Royal Aeronautical Society. Further information if required can be obtained by contacting Dr Simon Gill via HeliOffshore (Gretchen Haskins or Tim Rolfe).</p> <p>If there is limited appetite to address the full system for the possibility of maintenance errors at this time, this consideration could be incorporated only for the situations where the consequence of pilot error would be particularly severe. By analysis of the maintenance engineer tasks and minimising of human error opportunities there, this could reduce the likelihood of technical failure that creates the situation. One means to achieve this would be the abovementioned Human Hazard Analysis process where critical tasks on selected critical systems are selected for study.</p>	Review reference materials and consider inclusion of key concepts of reference as part of means of compliance. Contact Dr Simon Gill via HeliOffshore (Gretchen Haskins or Tim Rolfe) for further information.	Recommended	Noted	EASA thanked HeliOffshore for the provision of the information. An internal review is ongoing to investigate the mentioned studies. EASA kindly reminds that HF in Maintenance is not part of the scope of this CM. EASA also reminds that it is EASA philosophy to consider Human Factors as an holistic approach, this CM is considered as part of this holistic approach.
9	Rolls-Royce	-	-	The document speaks about FHA, but no reference to the ARP4761 is given. It might be useful to create this link.	Add Reference to ARP4761.	Recommended	Accepted	The reference will be added.

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10	Collins Avionics	1 & 3	1/3	<p>The scope seems to focus on situations where the aircraft under consideration is known. It is unclear how and with what scope this memo should be applied to system suppliers who may not have access to the same HF testing capabilities as an aircraft manufacturer.</p> <p>Similarly, system functionality and product development commonly occurs without a targeted aircraft application and therefore without a clear scope of what a representative pilot population may be across all potential applications. It is unclear how this guidance should be applied in these situations.</p>	<p>The document should clarify what means would be acceptable to perform by the system level suppliers who may not have access to the representative pilots or may be developing functionality without a specific aircraft use case.</p> <p>The scope of this memo should allow for system/product developers to participate in the process without the rigor that would be attached to considering every possible application.</p>	Requested	Not accepted	<p>The CM applies to Aircraft manufacturer (Applicant) and therefore the aircraft under consideration is known. The Aircraft manufacturer is expected to define and document the process used to manage the assumptions in safety assessments and consider the confirmation of the assumptions made about flight crew behaviour (Refer to paragraph 3.2).</p> <p>Suppliers developing system products should have in mind the category of aircraft as target as well as major design aspects and certification assumptions (CS25, CS23, SC VTOL,). However, it is understood that Suppliers may not have knowledge of the exact targeted aircraft application for their initial development.</p> <p>The system suppliers are expected to follow this CM at their best and to consider any expected flight crew behaviour according to their best understanding of the foreseen aircraft application. The assumptions and validation analyses should be at the disposition of the Aircraft manufacturer. It is typically part of a dedicated interface document. Further iterations might be necessary with the Aircraft manufacturer, the focus being the confirmation of the classification of the Failure Conditions.</p>
11	Honeywell	1.1	3	<p>It provides applicants with a structured <u>Human Factors methodology</u> to validate the assumptions made about the expected flight crew behaviours, in the aircraft and system Functional Hazard Assessments (FHA).</p> <p>Not an exact/appropriate description</p>	Change to: “Human Factors process” or “framework”	Recommended	Accepted	The change will be introduced, and the word methodology replaced by process.
12	Boeing	1.1	3	On Page 3, the phrase “expected flight crew behaviours” is used; it is unclear if this is equivalent to “expected flight crew response”.	Boeing requests that EASA add the definition for “flight crew behaviour” to Section 1.4: Definitions.	Requested	Not Accepted	The word behaviour is more generic than a response.

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13	Boeing	1.1	3	Boeing believes there is insufficient guidance to apply this validation technique to airplane level functional hazard assessments. Airplane level functional hazard assessments are more general than system level assessments, and inherently cannot have discrete actionable failure conditions due to the integrated aircraft functional level of the conditions. These more general failure conditions cannot be related to discrete crew actions and tasks that can be validated or tested unless the failure condition are further decomposed into sets of system level failure conditions.	Boeing requests the removal of AFHA from the CM applicability or the revision of the CM to provide guidance on suggested methodology for airplane level crew action assumption validation.	Requested	Not Accepted	The level of details of the Aircraft FHA varies from one applicant to the other. The certification memo has been written in such way that it would be compatible with all types of safety assessment process.
14	Heart Aerospace AB	1.1	3	On page 3, the Proposed CM-SA-002 states that “It provides applicants with a structured Human Factors methodology to validate the assumptions made about the expected flight crew behaviours, in the <u>aircraft and system Functional Hazard Assessments (FHA)</u> ”. AFHA and SFHA are not the only safety process that address the consideration of Human Factor mostly where explicit and unambiguous causal information would not be provided, quoted as Failure Management Case #2 in this CM. This is the case whenever a system failure results in cascading effects (bottom up) on other systems due to its implementation rather than functional top-down analyses through the Failure Conditions assessed in the AFHA and SFHA.	To be more consistent with the upcoming ARP4761A and ARP4754B, Heart Aerospace AB suggests that CEA (cascading effect analysis) methodology should also be required to support multi-systems and multi-functions analysis for cases not addressed by AFHA/SFHA processes.	Recommended	Accepted	The value of the CEA (cascading effect analysis) methodology is acknowledged, and EASA confirms the general intent to recognize the ARP4761A and ARP4754B when published.
15	Airbus	1.1	3	"aircraft and system Functional Hazard Assessments (FHA)" appears 2 lines above as "Aircraft and System..."	Propose to harmonise using uppercase for "Aircraft and System..."	Recommended	Accepted	Text amended accordingly.

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16	FAA AIR-710	1.1	3	Language in CM states: “It provides applicants with a structured human factors methodology to validate the assumptions...” The FAA does not mandate how the applicant document showings of compliance, only if the deliverable provides the minimum required to comply to the rule. Does EASA intend to use this CM for only EASA applicants?	Clarification within CM	Requested	Partially Accepted	EASA agrees that the applicant is responsible to document the showing of compliance. The word “methodology” has been replaced by “process” aiming to clarify that it is the process that needs to be implemented. There is no requirement into this CM regarding the way this process is to be documented. EASA confirms the intention to implement this CM to all applicants as defined in the paragraph 4 of this CM.
17	FAA AIR-710	1.1	3	Paragraph 2 has several bullets discussing flight crew aspects which are additional in scope to showings of compliance to 25.1309. It also uses language from AC25.1302-1. Is the intent for EASA to provide the applicant with the acceptable means and methods, or for the applicant to propose means and methods for EASA to accept? This paragraphs is in conflict with the title as well as the first paragraph in section 1.1	Clarification within CM	Requested	Not Accepted	EASA considers that there is no conflict. The CM provides framework for the applicant to establish and propose structured process and methods to substantiate the classification of the Failure Condition when classification takes credits from flight crew behaviours.
18	Gulfstream Aerospace Corporation	1.1	3	Reference to “cognitive aspects underlying the failure condition recognition” cannot be determined with any level of certainty as it is completely dependent on pilot or crew individual differences. An aircraft manufacturer has little to no control over pilot behaviour.	Delete this phrase and replace with “...material, including remaining flight deck equipment or safeguards available to aid in pilot decision-making.”	Requested	Not Accepted	The efficiency of the safeguards and other design features mentioned by GAC has to be assessed in relation with the cognitive needs of the situation. Therefore, the cognitive aspects underlining the FC need to be analysed and documented.
19	Gulfstream Aerospace Corporation	1.1	3	Reference to “establishing the criteria driving the level of scrutiny required ...” is a basic tenet of 25.1302 and new and novel equipment; it does not need to be re-referenced here for all safety analysis.	Delete this bullet – covered under 25.1302	Requested	Not accepted	The level of scrutiny is not a terminology that is specific to 25.1302. The criteria proposed by the applicant to determine the depth of the means selected to validate the assumptions about flight crew behaviours may be different from the ones provided in the context of 25.1302 demonstration.

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20	EMBRAER S.A.	1.1	3	One of the focus of this memorandum is on “establishing the criteria defining a new criteria for driving the level of scrutiny for assumptions validation based on confidence degree, use the existing criteria on AMC 25.1302.	Reference the criteria on AMC 25.1302 for defining the level of scrutiny for assumptions validation.	Recommended	Not accepted	The level of scrutiny is not a terminology that is specific to 25.1302. The criteria proposed by the applicant to determine the depth of the means selected to validate the assumptions about flight crew behaviours may be different from the ones provided in the context of 25.1302 demonstration.
21	TCCA - NAC	1.1	3	<p>The CM starts off talking about human factors, but focuses exclusively on flight crews. While the focus on flight crews is important, there should also be considerations for cabin crews, ground crews and maintenance personnel.</p> <p>AC 25.1309 Arsenal, AMC 25.1309 and the associated reference material (e.g. ARP 4754A/4761, ED 79/135) typically refer to crew member and maintenance personnel in their definition of errors. Additionally there have been aircraft accidents and incidents associated with human error which warrant further consideration. These would include rigging pins that were errantly left in place, large cargo doors that were not properly closed, and passenger doors that were opened under pressurization.</p>	<p>Suggestion:</p> <p>TCCA recognizes the benefit and value in this CM and the focus on flight crew human factors. However, some wording could be included that emphasizes that human error must still be assessed more broadly.</p>	Recommended	Not accepted	EASA believes the point is valid and that the assumptions made on for cabin crews, ground crews and maintenance personnel behaviours are relevant. The scope of this CM is however limited to flight crews. In order to clarify the subject, CM title is modified as “Flight Crew Human Factors Assumptions in Aircraft and System Safety Assessments”.

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22	TCCA - NAC	1.1	3	The introductory paragraph talks about the CM being applicable to Large Aeroplanes only. While TCCA concurs that the focus of the CM should be on large aeroplanes, it could also be applicable to other aircraft types, especially those that involve complex systems.	Consider expanding applicability to other aircraft categories, or adding wording that would explain the fundamentals of the CM would be relevant to any aircraft that has complex and highly integrated systems. Perhaps similar to wording to FAA AC 20-174. The guidelines in this CM were developed in the context of CS 25. It may be applicable to other regulations, such as CS 23, 27, and 29.	Recommended	Not accepted	EASA agrees with the principle that the consideration contained in the CM , could also be applicable to other aircraft types, especially those that involve complex systems however it is not currently within the scope of the CM. Should the scope be later enlarged, CM would be updated.
23	TCCA - NAC	1.1	p.3/11	“...identifying and defining the elements missing in the existing guidance material, incl. cognitive aspects underlying the failure condition recognition and the elaboration of the diagnosis of the situation,...” The quote above addresses only a subset of the aspects addressed in this CM. Referring to Table 1 entries (task analysis framework), shouldn’t flight crew response and post-failure management also be addressed?	Recommend adding the missing elements from Table 1 to section 1.1 (purpose and scope)	Recommended	Accepted	EASA concurs with the comment. The text was amended accordingly.
24	GE Aviation – Human Factors	1.1	3	The term “applicant” is unclear. Who is the “applicant” specifically? Individuals requesting certification?	Add “applicant” to the glossary for definition	Recommended	Not accepted	“applicant” is a standard term used in EASA documentation.

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25	UK CAA	1.1 Purpose and Scope 1.2 References	3	The proposed CM limits the scope to large aeroplanes but the problems it addresses, associated with Human Factors and Functional Hazard Analysis, are directly relevant to CS-23 Level 4 aeroplanes, particularly those approved for single pilot IFR operations. Although CS-23.2510 appears simpler than CS-25.1309, for a CS-23 Level 4 aeroplane the complexity and depth of the supporting FHA and Human Factors Assessments are, in practice, very similar to those required for a CS-25 aeroplane.	The CAA requests that the scope of the CM should be increased to include CS-23 Level 4 aeroplanes, at least to those intended to be approved (or with potential to be approved) for single pilot IFR operations.	Requested	Not accepted	EASA agrees with the principle, however it is not currently within the scope of the CM. Should the scope be later enlarged, CM would be updated.

26	General Aviation Manufacturers Association (GAMA)	1.1, 2.2, 3.1 (table 1), Sec 3.2 (table 2)	page 3, 5, 7, 8, 10	The proposed CM seems to use ambiguous terms and does not provide appropriate definitions that ensure correct, certain, conceptual interpretation by the applicants.	<p>EASA to include in Sec. 1.4 definitions the ambiguous terms used in the proposed text to ensure correct interpretation by the applicants. Namely:</p> <ul style="list-style-type: none"> - ‘Expected flight crew behaviour’, CM 1.1, page 3; - ‘Environmental conditions’, CM 2.2, page 5; - ‘Basic airmanship’, CM 3.1, table 1, page 7; - ‘Unusual workload’, CM 3.1, table 1, page 7; - ‘Unusual concentration’, CM 3.1, table 1, page 7; - ‘Primary failure’, CM 3.1, table 1, page 7 - ‘Comprehensive list’, CM 3.1, table 1, page 8. - ‘Verification’, CM 3.2, 1st paragraph (term is used with different interpretations throughout the document) - ‘Expert judgement’, CM 3.2, table 2 	Requested	<p>Not Accepted</p> <p>EASA is aware of the need to clarify the terms used, in this sense EASA added several definitions to the regular update of the CS25. However EASA considers the following terms as generic and self-explanatory: “deliverable”, “comprehensive list”, “panel experts”</p> <p>EASA does not see the need to precisely define nor provide specific metrics for: “unusual workload”, “unusual concentration”, “Expected flight crew behaviour”. The applicants are then free to develop and propose their own methods.</p> <p>“Environmental conditions” is considered tackled under AMC25.1309, therefore no additional definition is considered needed.</p> <p>“primary failure” is replaced by “initial failure” in the document.</p> <p>«expert judgement» has been replaced by «engineering judgement».</p> <p>“Basic airmanship” no agreed definition is available.</p> <p>“Verification” is already defined in the CM.</p>
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					<ul style="list-style-type: none"> - ‘Panel experts’, CM 3.2, page 8 - ‘Deliverable’, CM 3.2, table 2, page 10; 			
27	EMBRAER S.A.	1.2	3	Assumptions validation is also related to existing SAE documents: ARP4754A and ARP4761. References to these documents should be added.	Include references to ARP4754A and ARP4761 in section 1.2.	Recommended	Accepted	The references will be added to the document. Text edited §1.2 References.
28	Saab AB	1.4	4	What exactly is regarded as an assumption? E.g. SAE ARP4754A defines “Assumption” as Statements, principles, and/or premises offered without proof. To avoid misinterpretation and scope creep a definition would be useful.	Add EASA’s definition of assumption to section 1.4.	Requested	Not Accepted	Definitions are added to describe new concept or different definition of existing concept, which is not the case here for assumptions.
29	Saab AB	1.4	4	What exactly is regarded as an assumption? E.g. SAE ARP4754A defines “Assumption” as Statements, principles, and/or premises offered without proof. To avoid misinterpretation and scope creep a definition would be useful.	Add EASA’s definition of assumption to section 1.4.	Requested	Duplicate	Comment #29 to be removed, duplicate from #28.
30	Boeing	1.4	4	The definition: “Validate--Determine correctness and completeness” lacks context with how correctness or completeness are evaluated for FHAs	Boeing recommends that EASA clarify the definition of “validation” in the Definition table. Boeing recommends replacing the definition with: “Validate – Determine correctness and completeness of the flight crew expectations and assumptions.”	Recommended	Not accepted	The definition seems correct. If “validate” means “determine correctness and completeness”, then in the document it is clear that “validate assumptions about flight crew behaviour” means “determine correctness and completeness of assumptions about flight crew behaviour”.
31	Volocopter GmbH	1.4	4	Relevant sources or references for definitions should be provided. For example, AMC25.1309 for “Failure Condition” and ARP4754A for “validate” and “verify”	Provide references document for the definition	Recommended	Accepted	References added to the definitions.
32	Volocopter GmbH	1.4	4	The definition of “primary failure” which is in Table 1 of this CM is missing. Note that this term is not used neither in AMC 25.1322 nor in AMC 25.1309.	Add definition for “primary failure” in Section 1.4	Requested	Partially Accepted	“Primary failure” is replaced by “initial failure” in the document. Initial failure is considered self-explanatory.

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33	Airbus	1.4	4	Definition of "Failure Condition" is taken from AMC to 25.1309	Propose to notice that the definition is taken from the AMC: "A condition...events. [as per AMC to 25.1309]"	Recommended	Accepted	References added to the definitions.
34	Gulfstream Aerospace Corporation	1.4	4	<p>Definition of “Confidence degree: Perceived validity of the assumption from the review team based on the plausibility of the described expected crew behaviour.”</p> <p>Trying to predict crew behaviour or clinically diagnose a pilot cognitive state is an unrealistic, unattainable requirement and this criterion is so subjective it could never be applied in a standardized manner across OEMs or equipment designs. The focus should be on how use of the installed equipment is tied to intended function (a key principle of Part 25 certification) and the available information, alerting, or decision aids provided to influence flight crew decision making versus a focus on flight crew behaviour outcome which cannot be predicted with any certainty.</p>	Suggested rewording: “Confidence degree: Perceived validity of the assumption from the review team based on the design or function flight deck effects, potential for crew error, and safeguards available to mitigate crew error occurrence.”	Requested	Not accepted	<p>There seems to be a misunderstanding about what is a crew behaviour. This does not refer to “pilot cognitive states”, such as confusion, stress, fatigue or whatever, but to tangible elements that can be predicted and even expected by the applicants, which allow them to rely on those expected elements in order to determine the failure classification.</p> <p>A crew behaviour should be understood as an output of any of the cognitive processes, from the more basic to more complex ones, that are in play when a flight crew has to deal with a failure condition. The following shows a list of possible behaviours:</p> <ul style="list-style-type: none"> - Perception of a stimulus (example of expected behaviour: the crew is expected to detect a CAS message on a given display) - Diagnosis of the failure condition (example of expected behaviour: the crew is expected to understand that the failure X is active) - Flight crew response ((example of expected behaviour: the crew is expected to make an action, to run a procedure)
35	Airbus Helicopters	1.4	4	<p>“Validate and Verify,”</p> <p>make sure the definition are in accordance with the ones of ED-79A/B</p>	make sure the definition are in accordance with the ones of ED-79A/B	Recommended	Accepted	References added and in accordance with the material.

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36	ANAC	1.4	4	ANAC recommends adding the definition of assumption (either general, or specific to flight crew) to ensure consistent interpretation of the CM.	Suggest including definition of assumption in this section, preferably adopting the definition already presented in ARP4754A/ED-79A.	Recommended	Not accepted	Definitions are added to describe new concept or different definition of existing concept, which is not the case here for assumptions.
37	Collins Avionics	1.4	4	The definition of “Validate” should include reference to “ED79A/ARP4754A” so that the context of “...correctness and completeness” is in the proper context.	Include reference to ED79A/ARP4754A in the definition of “Validate”.	Recommended	Accepted	References added.
38	Collins Avionics	1.4	4	Based on Figure 1, it appears confidence degree is a categorical variable. The definition of “Confidence Degree” doesn’t contain details on the categorical options. It is unclear the options/unit of measure of “Confidence Degree”.	Consider including the possible categorical options within the definition (ex. Perceived validity of the assumption (low, high, very high) from the review team based on the plausibility of the described expected crew behaviour.	Requested	Not accepted	It is on purpose that EASA is not prescriptive regarding the way to quantify the confidence degree. It is for the applicants to propose their own categories.
39	ADSE B.V. The Netherlands	1.4 Definitions	4	Please add a definition of human error to avoid misconception about the term: Human Error: A human action with unintended consequences. A human error can be a slip (attentional failure), a lapse (memory failure) or a mistake (either applying a bad rule or applying insufficient knowledge).		Requested	Accepted	Definition added: human error: a deviation from what is considered correct in some context, especially in the hindsight of the analysis of accidents, incidents, or other events of interest. Some types of human error may be the following: an inappropriate action, a difference from what is expected in a procedure, an incorrect decision, an incorrect keystroke, or an omission.
40	Rolls-Royce	2	5	Reference to ARP4754A is given. As this in the process of being updated, it might be helpful to say: ARP4754 in the latest or applicable revision.			Accepted	“or the latest revision” is added.

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41	Dassault Aviation	2.1	4	Human error should not be combined with failure case in the FHA / SSA. Human error are to be assessed during HF analysis. If it is likely that an error occur, the human behaviour assumption should be rechallenged	Remove the sentence “any additional hazard that could result from human errors while the failure condition is being managed.”	Requested	Not accepted	This is 25.1309(c) verbiage, there is no reason for removing it. Furthermore, there is no intent to combine human error with failure conditions to determine their classification. The intent is to ensure that all the behaviours that are expected from the flight crew in order to cope with the failure condition are likely to realize.
42	Honeywell	2.1	4	The consequences of failure conditions or functional failure scenario1 and their severity may be mitigated by relying on flight crew actions. Whether these mitigations trigger the expected effect directly affects the classification, and subsequently the safety objectives	Suggest to add the following text: To determine the degree to which the flight crew is used to mitigate the outcome of a failure condition, the applicant should describe the severity of the effects of the failure condition without pilot response and the severity of the effects of the failure condition after the defined pilot response. The bigger the difference in severities the higher should be the required HF scrutiny for assumptions on pilot behavior.	Requested	Not accepted	EASA considers that there is no direct link between the delta severity (failure condition severity with and without pilot response) and required scrutiny on flight crew behaviour assumptions.

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43	Volocopter GmbH	2.1	4	<p>“The consequences of failure conditions or functional failure scenario and their severity may be mitigated by relying on flight crew actions. Whether these mitigations trigger the expected effect directly affects the classification, and subsequently the safety objectives”</p> <p>The level of resulting crew workload also directly affects the severity classification, as per AMC25.1309 section 8.b for the effect on Flight Crew and AMC25.1309 section 9.b.(5).3.(iii). However, this memo addresses this topic only once in Table 1 (post-failure management). It is not understood why assumptions made in the FHAs related to crew workload assessment are not considered in the scope of this CM, as part of the general assumptions on “pilot's behaviour”.</p>	Precise if assumptions related to crew workload made in the FHA have to be considered under the general guidance provided by this CM for the activities for validation of assumption on “pilot’s behaviour” carried on by the Human Factors specialists in accordance with AMC25.1302.	Requested	Accepted	It is agreed that the assumption on “pilot’s behaviour” include of the consideration of the crew workload and that it directly affects the severity classification. The actual workload has an impact which is not limited to the post-failure management as it can influence the step 3 with information processing or step 4 with the flight crew response.
44	FAA AIR-633	2.1	4	Paragraph 2 under 2.1 “severity may be mitigated by relying on flight crew actions”. Mitigation depends, as noted later, on other factors like flight crew recognition, knowledge and skill.	Revise 1 st sentence paragraph 2: The consequences of failure conditions or functional failure scenario ¹ and their severity may be mitigated by relying on flight crew recognition and response actions.	Requested	Accepted	EASA concurs with the comment. The text has been amended accordingly.
45	FAA AIR-633	2.1	4	Paragraph 4 under 2.1 – last bullet: “- sufficient time to address the failure condition” sufficient time should include time to recognize as well as to act.	Revise last bullet – sufficient time to establish a valid interpretation of the situation and perform the corrective action necessary to address the failure condition.	Requested	Accepted	EASA concurs with the comment. The text has been amended accordingly.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
46	FAA AIR-633	2.1	4	Paragraph 6 under 2.1 – specific safety assessment of interest not identified. Expanded scope of CM beyond what is identified in paragraph 1.	Revise paragraph: These disparities may invalidate the assumptions made in the FHA safety assessment and ultimately the validity of other assessments. Most applicants do not conduct any systematic and structured activity to demonstrate the validity of FHA assumptions.	Requested	Accepted	EASA concurs with the comment. The text has been amended accordingly and reads “These disparities may invalidate the assumptions made in Aircraft and System FHA and ultimately the validity of other assessments. Most applicants do not conduct any systematic and structured activity to demonstrate the validity of FHA assumptions.”
47	Bombardier	2.1	4	<p>“These prerequisites are usually considered by applicants in aircraft and system FHAs as implicitly given and fulfilled by default” .</p> <p>This sentence does not reflect the processes put in place by applicants to substantiate failure condition classification. Current FHA processes ensure that evidence is produced in support of failure condition classification, and that includes those failure conditions for which the effects are mitigated by crew behavior.</p>	Remove the sentence.	Requested	Not accepted	It is agreed that the current FHA processes should ensure that evidence is produced in support of failure condition classification. Experience show that the prerequisites listed in the CM for a proper application of corrective actions are sometimes considered by applicants in Aircraft and System FHAs as implicitly given and verified in another processes that are not directly connected to the FHAs.

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48	Bombardier	2.1	4	<p>“These assumptions may be indirectly validated or verified in other processes that are not directly connected to the FHAs”. Validation and verification processes apply to requirements and not to assumptions. While assumptions may justify and provide rationale for requirements, they are not by themselves requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified).</p>	Change the sentence to state that “assumptions may be indirectly confirmed in other processes (...)”.	Requested	Accepted	<p>The intent was to align the terminology used in this CM to the maximum extent possible with industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135. At the time of drafting of the CM, the direction that the standardization bodies were taking was not fully defined. Since then, the maturity of the SAE/EUROCAE discussion have progressed and it is clear that the consensus wording will be “confirmed”. The text has been updated accordingly. In addition the introduction was updated and reads “Therefore, no existing guidance material either in CS 25.1309 or in CS 25.1302 provides dedicated and structured human factors process for confirming the assumptions made by applicants about flight crew behaviours in Aircraft and System FHAs.”</p>
49	Bombardier	2.1	4	<p>“These disparities may invalidate the assumptions made in the safety assessment and ultimately the validity of these assessments”.</p> <p>The reference to safety assessment in this sentence is not clear as to whether it implies the safety assessment process or a specific safety assessment document.</p>	Change the sentence to refer to “the safety assessment process”.	Requested	Noted	<p>It implies the safety assessment process, in particular the classification of the failure conditions in the aircraft and system FHA.</p> <p>Text reworded to add clarity.</p>

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50	ANAC	2.1	4	The concept of “functional failure scenario” in lieu of (or equivalent to) failure conditions is not directly referred in the published rules and guidance associate to system safety and/or human factors. The footnote provides a short explanation, but it is not clear which kind of “several scenarios” are concerned in this context. Since this concept is not directly recognizable in AMC 25.1309, it might be the case that these terms may be too applicant-specific.	Suggest changing sentence to broader terms: “The consequences of failure conditions (or equivalent, depending on each applicant’s safety process) and their severity may be mitigated ...” OR Further expand on what a functional failure scenario is, and whether other alternatives for identification of “failure conditions” would be acceptable as well.	Recommended	Accepted	Text reworded
51	ANAC	2.1	4	Section 2.1 lists three prerequisites for a proper application of corrective actions from a cognitive standpoint. However, other aspects beyond cognitive, such as non-exceptional pilot skill and strength, workload, etc. are also important but not listed.	Consider adding a new paragraph to include non-exceptional pilot skill or strength, workload, an others as appropriate in the list of prerequisites for proper application of corrective actions in this section.	Recommended	Not accepted	Considerations are too detailed for a cert memo and they are covered in the aspects of the CS 25.1302.

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52	ANAC	2.1	4	Section 2.1, third paragraph, mentions CS 25.1309(b) and (c). However, since such paragraph also mentions human errors, CS 25.1302 should also be listed. It is worth mentioning that CS 25.1302 is called out in Section 2.2 when referring to flight crew errors.	Consider adding CS 25.1302 along with CS 25.1309(b) and (c) in the third paragraph.	Recommended	Noted	This paragraph underlines that the flight crew recognition and response after a occurrence of a failure or failure condition may affect the hazard classification (as reference in the AMC 25.1309 b). From a certification standpoint, those aspects are covered by a combination of CS 25.1309(b) and CS 25.1309(c).
53	EMBRAER S.A.	2.1	4	It is not clear in the document the definition of flight crew “action”, “behaviours” and “response”. They are also being used in other sections of the document.	<p>Include definitions of “flight crew action”, “flight crew behaviours” and “flight crew response” in section 1.4. For example:</p> <p>Flight crew action: The movement performed by the flight crew, which is externally observable.</p> <p>Flight crew behaviour: The manner that flight crew conducts themselves, involving response to stimulation.</p> <p>Flight crew response: The activity accomplished due to the presentation of an alert such as an action, decision, prioritisation, or search for additional information (AMC 25.1322).</p>	Requested	Not accepted.	EASA believes “action”, “behaviours” and “response” are generic terms used across the industry and do not require specific definition in the context of this CM.

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54	EMBRAER S.A.	2.1 3 3.1	4 5 5	<p>It seems that the terms flight crew “action” and “response” are being used interchangeably throughout the document, which contradicts with their definitions in AMC 25.1322, where both terms have different meanings.</p> <p>The text “flight crew recognition” should also be modified to harmonize with the definitions in AMC 25.1302.</p>	<p>Section 2.1:</p> <p>FROM: “flight crew recognition, interpretation, and response”</p> <p>TO: “flight crew awareness, interpretation, and action”</p> <p>Section 3:</p> <p>FROM: “flight crew recognition and/or action”</p> <p>TO: “flight crew awareness and action”</p> <p>Section 3.1:</p> <p>FROM: “flight crew response, and”</p> <p>TO: “flight crew action, and”</p>	Recommended	Not accepted.	See EASA answer to comment #53.
55	HeliOffshore	2.1	4	Prerequisites - In the list of preconditions (e.g. recognition of problem), for completeness it could be useful to add that the pilot must know what to do in response to the situation.	Add text to acknowledge that the pilot must know what to do in response to the situation as an additional bullet in the prerequisites list.	Requested	Accepted	The Crew has to be trained and aware of the procedure. This is a key assumption and will be added for completeness.

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56	TCCA - NAC	2.1	p.4/11	“The severity consequences of some failure conditions or functional failure scenario and their severity may be mitigated by relying on flight crew actions. <u>In such cases, flight crew actions would therefore</u> Whether these mitigations trigger the expected effect directly affects the <u>hazard</u> classification, and subsequently the safety objectives. The <u>adequacy expected effects</u> of such mitigations depends on the capability of flight crews to perform the actions that are expected from them, and the ...”	Recommended rewording, as noted in comment, to improve flow and clarity. Recommended rewording for clarity. See markups in proposed resolution.	Recommended	Accepted	The paragraph will be updated accordingly.
57	TCCA - NAC	2.1	4	Existing wording: The consequences of failure conditions or functional failure scenario and their severity may be mitigated by relying on flight crew actions. Whether these mitigations trigger the expected effect directly affects the classification, and subsequently the safety objectives.	Proposed wording: The consequences of failure conditions or functional failure scenarios and their severities may be mitigated by relying on flight crew actions. Whether these mitigations trigger the expected effect directly affects the classification, and subsequently the safety objectives.	Recommended	Accepted	The paragraph will be updated accordingly.
58	GE Aviation – Human Factors	2.1	4	The phrase “valid interpretation of the situation” can be misleading. A pilot can have a valid interpretation of what is happening based on the circumstances but that does not necessarily mean it is accurate, which could lead to applying an incorrect corrective action.	Reword “valid interpretation of the situation” to “accurate identification of the situation”.	Recommended	Partially Accepted	The word will be replaced by “appropriate” because “accurate” may point to a precise understanding of the situation which is not what is targeted at this stage.

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59	Gulfstream Aerospace Corporation	2.1, Paragraph 5, Sentence 2	4	<p>“These assumptions may be indirectly validated or verified in other processes...”</p> <p>Section 1.4 defines “verify” as an act to evaluate the implementation of requirements, not assumptions. This definition is aligned with EUROCAE ED-79 / SAE ARP 4754. Validation, on the other hand, is applicable to both requirements and assumptions, since the objective is to determine their correctness and completeness.</p>	Remove “or verified” from this sentence OR reword this sentence to “These assumptions may be indirectly validated and their associated requirements verified in other processes [...]”.	Requested	Accepted	Text reworded
60	Dassault Aviation	2.2	5	<p>Since it is almost impossible to systematically combine all foreseeable human errors and failure conditions, the error analysis in safety assessment process should be limited to the most likely one due to weakness in the design or in procedure .</p>	Add “marginally” -> “where marginally relevant”	Recommended	Not Accepted	We agree that all foreseeable human errors and failure conditions cannot be assessed. However the paragraph 2.2 already refers to “where relevant and appropriate”.

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61	Boeing	2.2	5	<p>On Page 5, EASA states “Whenever credit is sought from flight deck effects and/or flight crew actions when assessing system failure conditions for compliance with CS 25.1309(b), the related AMC requests to verify that:</p> <ul style="list-style-type: none"> any identified indications will, in fact, be recognised, any actions required have a reasonable expectation of being accomplished successfully and in a timely manner.” <p>The definition of “timely manner” varies across flight conditions and failure conditions.</p>	<p>Boeing requests that EASA update “timely manner” to “timely manner, appropriate for the condition” so the entry reads “Whenever credit is sought from flight deck effects and/or flight crew actions when assessing system failure conditions for compliance with CS 25.1309(b), the related AMC requests to verify that:</p> <ul style="list-style-type: none"> any identified indications will, in fact, be recognised, any actions required have a reasonable expectation of being accomplished successfully and in a timely manner, appropriate for the condition.” 	Requested	Accepted	Text reworded
62	Boeing	2.2	5	<p>On Page 5, the CM states “The Agency position is that the non-normal conditions due to system failures and malfunctions should be addressed in addition to environmental conditions.”</p>	<p>Boeing requests that EASA add the definition for “environmental conditions” in the context of this Certification Memorandum to Section 1.4: Definitions.</p>	Requested	Not Accepted	The definition of environmental conditions is not specific to this CM and is similar to the one used in the context of CS25.1309 compliance demonstration.

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63	Boeing	2.2	5	On Page 5, the CM states “The Agency position is that the non-normal conditions due to system failures and malfunctions should be addressed in addition to environmental conditions.”	Boeing requests EASA to outline the expectations for what environmental conditions should be addressed.	Requested	Not Accepted	The definition of environmental conditions is not specific to this CM and is similar to the one used in the context of CS25.1309 compliance demonstration.
64	FAA AIR-633	2.2	5	“Whenever credit is sought from flight deck effects and/or flight crew actions...” Unsure how one can analyze mitigation credit credit from ‘flight deck effects’ which are typically observations	Whenever credit is sought from flight crew actions...	recommended	Accepted	Text reworded “...Whenever credit is sought from flight crew recognition of flight deck effects and/or flight crew actions”
65	FAA AIR-633	2.2	5	Paragraph 3 – “ should be used where relevant and appropriate...”As this CM is establishing a methodology to validate the assumptions should it also identify which HF 25.1302 assessments are “relevant and appropriate”	Revised paragraph to identify the specific 25.1302 assessments would be consider relevant and appropriate.	Recommended	Not Accepted	EASA considers that it is applicant’s responsibility to identify if and which data coming from 25.1302 assessments are appropriate and relevant.

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66	Airbus Helicopters	2.2	5	<p>The CM states that:“ The efficient recognition of a failure condition and the human performance aspects related to the management of this failure condition are indirectly covered per CS 25.1302.”</p> <p>Comment: The AMC 29.1302 is written as follows: “This AMC applies to crew member interfaces and system behaviour for all the installed systems and equipment used by the crew members in the cockpit and the cabin while operating the rotorcraft in normal, abnormal/malfunction and emergency conditions. (...) vi) The objective for the equipment to be designed so that the crew members can safely perform their tasks associated with the intended function of the equipment applies in normal, abnormal/malfunction and emergency conditions. The tasks intended to be performed under all the above conditions are generally those prescribed by the crew member procedures. The phrase ‘safely perform their tasks’ is intended to describe one of the safety objectives of this certification specification. The objective is for the equipment design to enable the crew members to perform their tasks with sufficient accuracy and in a timely manner, without unduly interfering with their other required tasks. The phrase ‘tasks associated with its intended function is intended to characterise either the tasks required to operate the equipment or the tasks for which the intended function of the equipment provides support.”</p>	Propose to clarify if the quoted § is the one that is designated in the CM.	Recommended	Noted.	The CM is applicable to Large Aircraft. The reference is made to CS 25.1302 and to the AMC 25.1302.
67	Airbus Helicopters	2.2	5	<p>The CM states that :“ The related AMC materials state that both normal and non-normal conditions are to be considered, without defining however what non-normal conditions are to be considered for that compliance demonstration,”</p> <p>Comment: The AMC 29.1302 includes this definition: “abnormal/malfunction or emergency conditions: for the purposes of this AMC, abnormal/malfunction or emergency operating conditions refer to conditions that do require the crew to apply procedures different from the normal procedures included in the rotorcraft flight manual (RFM).”</p>	Propose to clarify which is the appropriate guidance regarding these notions "normal and non-normal", "abnormal/malfunction or emergency conditions".	Recommended	Noted	The related AMC material for CS 25.1302 provides a definition “Tasks intended for performance under non-normal conditions are generally those prescribed by non-normal (including emergency) flight crew procedures”.

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68	Bombardier	2.2	5	<p>“As both CS 25.1302 and CS 25.1309 are dealing with human performance including human errors, the results of the assessments performed to address CS 25.1302 or equivalent, should be used where relevant and appropriate to complement the human error portion of the safety assessment process.”</p> <p>This sentence should clarify that “the human error portion of the safety assessment process” relates specifically to CS 25.1309(c). The FHA process, which is part of compliance with CS 25.1309(b), is not intended for the assessment of potential consequences associated to flight crew errors.</p>	Add at the end of the sentence “, in the scope of CS 25.1309(c)”.	Requested	Partially accepted	It is true that the FHA process is not intended for the assessment of potential consequences associated to flight crew errors. Nevertheless the results of the assessment could be used to validate the assumptions in the FHA.
69	Bombardier	2.2	5	<p>“Therefore, no existing guidance material either in CS 25.1309 or in CS 25.1302 provides a dedicated and structured human factors methodology for validating the assumptions made by applicants about flight crew behaviours in aircraft and system FHAs. Some general guidance on the management and validation of assumptions can be found in ED79A/ARP4754A, paragraph 5.4.2.d.”</p> <p>The validation process is intended for requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified). The ED79A/ARP4754A section referenced in the above quote is now titled “Management of Assumptions” in draft ED79B/ARP4754B (now section 5.4.2.4).</p>	Change sentence to state “(...) methodology for confirming the assumptions (...)”.	Requested	Accepted	Text reworded

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70	EMBRAER S.A.	2.2	5	The methodology proposed herein adds a tremendous amount of information for commercial air planes manufacturers for compliance demonstration to §25.1309, since it does not provide adequate limits in regards to the numbers of failure conditions addressed by current FHA’s. The document does not demonstrate the positive enhancement in safety, if any, by adopting the methodology proposed in the current Certification Memo versus the guidance on the management and validation of assumptions found in ED79A/ARP4754A.	EASA should provide rationale on the expected safety enhancements by air plane manufactures adopting the methodology proposed in the current Certification Memo to substantiate the increasing levels of information generated for compliance demonstration to §25.1309.	Requested	Not accepted	KNKT recommended to review assumptions on flight crew behaviour used during design and revise certification processes to ensure assumptions used during the design process are validated. (Boeing assumption was different from the flight crew behaviour and reaction time in responding to MCAS activation.) (ref. 04.R-2018-35.24). Cert Memo is one element to address the subject matter.
71	TCCA - NAC	2.2	5	This paragraph discuss the influence of normal and non-normal conditions in the analysis as per CS 25.1309 and CS 25.1302. However, some baseline guidance should be given to determine what is considered normal and what is considered non-normal.	Some guidance needs to be provided to determine what is considered normal conditions and/or non-normal conditions. If the purpose of this document is to increase the Human Factors considerations when applying these two analysis, then this needs to be defined.	Recommended	Not accepted	As described in the AMC for CS25.1032, Tasks intended for performance under non-normal conditions are generally those prescribed by non-normal (including emergency) flight crew procedures.
72	TCCA - NAC	2.2	p.5/11	“Whenever credit is sought from <u>flight crew recognition of</u> flight deck effects and/or flight crew actions when assessing system failure conditions for compliance with CS 25.1309(b)...” Credit wouldn’t be sought directly for flight deck effects, but rather for the crew’s recognition of these.	Should be reworded for clarity, as noted in comment.	Requested	Accepted	Reworded
73	TCCA - NAC	2.2	p.5/11	“... without defining however <u>which</u> what non-normal conditions are to be considered for that compliance demonstration...”	Recommended rewording (syntax), as noted in comment.	Recommended	Accepted	Reworded

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74	General Aviation Manufacturers Association (GAMA)	2.2 3 rd paragraph	5	There is no specific "human error portion" in the Safety Assessment process beyond some evaluation that the actions required have a reasonable expectation of being accomplished. There is no “human error portion” described in advisory material or industry practice.	EASA to remove this reference. The CM is specific to FHAs, and that reference seems to include more than FHAs.	Requested	Accepted	Text modified to provide more clarity.
75	General Aviation Manufacturers Association (GAMA)	2.2 4 th paragraph	5	EASA’s statement “...should be addressed in addition to environmental conditions” seems vague. It is not clear if the expectation is to combine them, and if yes, to what extent.	EASA to specify more explicit expectations for addressing “in addition to” to scope the appropriate combinations based on flight segment.	Requested	Accepted	Text reworded in accordance with the definition of failure condition according to AMC 25.1309. Expectation is to combine them, as also indicated by AMC 25.1309 (10) (c) (1) (ii).
76	TCCA - NAC	2.2, and similar references throughout the CM	p.5/11	“...any identified indications will, in fact, be recognised...” The term ‘indication’ would usually be understood as referring specifically to dedicated cockpit informations, alerting or annunciations. However from the broader contents of the document it seems the intent is to also cover other cues providing the flight crew information about the existence of a failure. TCCA concurs with this broader intent, but the use of the term ‘indication’ is confusing. It is noted CS 25.1309(c) now refers only to “information concerning unsafe system operating condition” and avoid previous references to “warning indications”. Also, AMC 25.1309 9.c clarifies: “The required information may be provided by dedicated indication and/or annunciation or made apparent to the flight crew by the inherent aeroplane/systems responses.”	Terminology throughout the document should be realigned with CS 25.1309(c) and corresponding AMC to avoid confusion, i.e. by referring to the broader notion of “information” instead of the narrower term “indication”, unless where intended specifically to address explicit CAS messages.	Requested	Not accepted	TALK with the group (go through the text and clarify if indication should be modified with information) For EASA, both indications and other information available to the crew are of interest. From EASA perspective, flight deck effects are mentioned and intended to cover these additional information.

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77	Gulfstream Aerospace Corporation	2.2, Paragraph 3, Sentence 3	5	<p>“The Agency position is that the non-normal conditions due to system failures and malfunctions should be addressed in addition to environmental conditions.”</p> <p>This sentence can be misinterpreted by guiding the FHA to consider all combinations of failures and malfunctions with all environmental conditions. However, there are combinations that are not applicable and they would add no value to the FHA.</p>	Clarify the intent of this sentence by rewording to “The Agency position [...] in addition to environmental conditions that are pertinent to the scenario being evaluated”.	Requested	Accepted	text reworded
78	Boeing	2.2.3	5	There is no specific "human error portion" in the Safety Assessment process beyond some evaluation that the actions required have a reasonable expectation of being accomplished. There is no “human error portion” described in advisory material or industry practice.	Boeing recommends removing this from the CM. This CM is specific to FHAs; the addition of this seems to include more than the FHAs.	Requested	Accepted	Text modified to provide more clarity (see comment #74)
79	Boeing	2.2.4	5	Boeing believe “...should be addressed in addition to environmental conditions” is vague. The interpretation can set an expectation to combine them, and if so there is no guidance on when to stop combining them.	Boeing requests that EASA specify more explicit expectations for addressing “in addition to” to scope the appropriate combinations based on flight segment.	Requested	Accepted	Text reworded in accordance with the definition of failure condition according to AMC 25.1309. Expectation is to combine them, as also indicated by AMC 25.1309 (10) (c) (1) (ii) (see comment #75)
80	Boeing	2nd sentence	6	The CM states “the applicant should provide the full set of information described in Table 1”.	Boeing requests EASA to clarify if it is expected to have the results of the Table 1 questions kept with the relevant SSA or as a supplement to the FHA.	Requested	Not accepted.	Cert Memo generally do not give guidance where Applicants should record information as it depends widely between Applicants on the overall document structure.

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81	Boeing	3	5	The CM states it applies to failure conditions which take credit for crew recognition and/or behavior. It is implied that the CM does not apply to failure conditions that recognize there is crew action that could be taken, but that action does not mitigate/address the failure. Boeing requests clarification on what types of assumptions require validation and which ones do not.	It is requested that EASA change the CM to clearly state that crew assumptions related to actions that could be taken, but do not mitigate/address the failure condition, do not require the applicant to demonstrate the validity of those assumptions.	Requested	Not accepted	CM scope is to establish criteria driving the level of scrutiny required to demonstrate the validity of certain assumptions. It does not imply that applicant is not required to validate the assumptions.
82	Volocopter GmbH	3	5	“It applies to all failure conditions which consider flight crew recognition and/or action with a particular emphasis on scenarios taking credit of crew behaviour when defining the severity classification.” Same comment as #3. Why this CM does not apply to scenario considering pilot’s workload as a driving criteria for the severity classification?	Suggest to add “scenarios taking credit of flight crew behaviour or workload , when defining the severity classification”	Requested	Accepted	See EASA response to comment #43.
83	Volocopter GmbH	3	6	It is not clear what is the relationship between this Certification Memorandum and AMCs (others than AMC 25.1309) that already consider pilot’s recognition and reaction in the Failure Conditions validation and propose standard criteria for the pilot’s reaction times, such as AMC to CS 25.1329.	Clarify relationships with others AMCs proposing an existing process for validation of Failure Conditions including assumptions on pilot’s behaviour and reaction times.	Requested	Not accepted.	Certification Memoranda clarify the EASA’s general course of action on specific certification items. They are intended to provide guidance on a particular subject and, as non-binding material, may provide complementary information and guidance for compliance demonstration with current standards. Certification Memoranda are provided for information purposes only and must not be misconstrued as formally adopted Acceptable Means of Compliance (AMC) or as Guidance Material (GM). Certification Memoranda are not intended to introduce new certification requirements or to modify existing certification requirements.

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84	Airbus	3	5	"EASA Certification Policy". The CM is supposed to propose guidance.	Propose to replace "EASA Certification Policy " " by "EASA proposed Guidance "	Requested	Not accepted.	Certification Memoranda are intended to provide guidance on a particular subject and, as non-binding material, and may provide complementary information and guidance for compliance demonstration with current standards. In addition, Certification Memoranda clarify the general course of action on specific certification items (policy). It was elected to use policy instead of guidance as title of this paragraph as it refers to EASA.
85	FAA AIR-633	3	5	This CM does not address the creation of the FHA human factor assumptions and their characteristics directly. It focuses on the evaluation during the verification phase. This is not clear as presented.	This CM applies only to the finding of safety assessment compliance portion of the development cycle. The applicant is expected to enhance current FHA guideline information of human factor elements to support the task analysis framework established herein.	Recommended	Noted	Scope of this CM is to provide applicants with a structured human factors methodology to validate assumptions made about the expected flight crew behaviours.
86	EMBRAER S.A.	3	5	The Certification Memorandum applies to “all failure conditions which consider flight crew recognition and/or action”. However, substantial information will require communication to certification authorities, based on Table 1, for conditions that have Minor or No safety effect and/or contain very high degree of confidence on expected crew behaviours. This increasing level of information without focusing on the critical data, does not foster improvements on the overall quality of assumptions validation process.	On Table 1, define adequate levels of information required to be communicated for assumptions validation process, based on the level of scrutiny.	Recommended	Noted	The Cert Memo applies to all the failure conditions with a criticality no less severe than MINOR.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
87	Collins Avionics	3	5	<p>“It applies to all failure conditions which consider flight crew recognition ...” The applicability of this guidance does not exempt areas where application of the process is irrelevant to the FHA’s validity. Notably, the following may be areas where the application of this guidance could be exempted.</p> <ul style="list-style-type: none"> - What about failure conditions that recognise flight crew recognition/action in their stated effects, but do not leverage the flight crew as a mitigation when determining the failure condition classification ? - What about those failure conditions whose classification is already driven by regulatory guidance ? Does this imply AC/AMC/TSO derived classifications may no longer necessarily represent a means of compliance ? - What about failure conditions of low severity or the flight crew mitigation consideration is an insignificant consideration (ie. Reduces from Minor to NSE)? The proposed process applies to all areas equally without applying focus to areas with increased credit for flight crew mitigations. <p>Failure conditions considered Catastrophic with or without a flight crew consideration should be exempt since there is no further escalation of criticality.</p>	<p>The scope of the guidance that is required should be only for those areas where flight crew mitigation of a failure condition is considered as a mitigating factor for the failure condition severity. Areas beyond this should be considered as additionally validation of the FHA, but not strictly required for compliance.</p> <p>Suggest developing additional guidance which aims to examine those cases where significant credit for flight crew mitigation is leveraged for a failure condition classification. This could be analogous to how safety assessments lower their level of scrutiny for lower level failure conditions</p> <p>Guidance should be provided on the applicability of this process where existing regulatory guidance currently exists.</p>	Requested	Noted	The Applicant has to define the scope within his process and when it is considered relevant that additional effort is put on the confirmation of the assumption. It is agreed that the focus should be for those areas where flight crew mitigation of a failure condition is considered as a mitigating factor for the failure condition severity.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
88	Dassault Aviation	3.1 Table 1	7	Failure case #1: The use of a proven (CS 25.1322 compliant) flight crew alerting mechanism, with visual cues in primary field of view, multisensorial, easily detectable by both crew members and triggering operating technique / memory items should be include in the scope of case 1 and thus not limited to the CAS messages	Do not limit the definition of an explicit crew alerting to a CAS message	Requested	Not accepted.	Current CM wording states “Explicit alert from the Crew Alerting System (CAS) unambiguously pointing to the initial failure”, hence text is not limiting the alert to a CAS message.
89	Dassault Aviation	3.1 Table 1	7	Primary failure may be subject to various interpretations: is it system failure or can it be an adverse condition (e.g. probe icing). We would prefer “root cause” to embrace both cases.	Add a definition of “primary failure” or rename it “root cause” (to be defined also)	Recommended	Partially accepted.	The wording “primary failure” was replaced by initial failure.
90	Dassault Aviation	3.1 Table 1	7	Precise what procedure implies. Confirm it embrace abnormal procedure , emergency procedure , operating techniques and memory items	Precise what a procedure implies	Requested	Not accepted.	Procedure indeed includes abnormal, emergency, memory items and operating techniques procedures.
91	Dassault Aviation	3.1 Table 1	7	Post failure management “inoperative systems, unavailable systems”: from the crew perspective, we should rather mention functional capabilities consequences rather than an equipment or system status which sometimes is not explicit in term of effect on the continuation of the mission or flight	Reword “inoperative system “ by “ function limitation or lost”	Recommended	Not accepted	EASA considers that both dimensions need to be addressed (the effect on the aircraft and the associated operational limitations) as reflected in the two bullets: “ What are the consequences of the failure condition on the aircraft systems (inoperative systems, unavailable systems, reversibility of the status, etc.)? What are the operational limitations to be respected due to the failure?”
92	Boeing	3.1	6	On Page 5, the CM states “This model, developed by EASA, provides an acceptable structured framework supporting a systemic assessment of the failure management. Alternative methods or frameworks should be Agreed with the Agency.” On Page 6, the CM states that the applicant should provide the full set of information described in Table 1. These statements seem to conflict with eachout.	Boeing requests that EASA add clarification in Section 3.1 – if all questions in Table 1 must be included in the applicant’s method or framework to satisfy the Certification Memorandum.	Requested	Not Accepted.	See EASA response to comment #97

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93	FAA AIR-633	3.1	5	Paragraph 1 under 3.1 - Table 1 does not adequately address the aircraft development process whereby AFHA and SFHA creation occurs agnostic of the planned architectures and implementations.	Add note or text to highlight that the inputs to this task analysis framework include completed FHA evaluations, completed safety assessments, completed or ongoing HF assessments or testing.	Recommended	Noted	This is clarified by text in section 3.2.
94	FAA AIR-633	3.1	5	Paragraph 1 under 3.1 last sentence before bullets: “five following phases” – phase implies time when expectation is only different steps.	Revise bullet intro to: The task analysis model is distributed among the five following steps:	Requested	Accepted	Text reworded
95	Airbus Helicopters	3.1	5	The CM states that: “Alternative methods or frameworks should be Agreed with the Agency” Comment: this is contradictory with the first page of the CM which mentions the CM is “non-binding material, may provide complementary information and guidance for compliance demonstration with current standards.”	Please adjust the wording about the need of alternative methods agreement and the nature of CM as guidance material (non-binding).	Requested	Noted	The wording in the CM was amended. The word ‘should’ is used in several sentences.
96	Airbus Helicopters	3.1	6	The CM states that: “For each applicable system failure condition, and based task analysis framework, the applicant should provide the full set of information described in Table 1” Comment: Propose the application of Table 1 framework for each and every FC in A/C and/or system FHA is tremendous job which seems difficult to sustain in long term.	Limit this assessment to failure scenario instead of FCs.	Requested	Noted	The application of the Table 1 is limited to failure conditions or functional failure scenarios whose repercussions can be mitigated by flight crew recognition and response. The scope of the assessment as per Table 1 is therefore limited.

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97	Airbus Helicopters	3.1	7	Table 1. Comment: The table 1 present a sort of checklist, possibly not exhaustive. The two cases would not be easy to handle (as it is stated, the condition of interest could be in between). Moreover, they are other factors influencing the management of the failure without being mentioned into additional columns. This table should be considered as an example instead of “an acceptable structured framework”, hence the Applicant should not have to justify the usage of another framework as far as it answered the objectives of the 1309. The CM should point the topics to be addressed to describe the FC, conduct the analysis and draw the conclusion. The checklist form is not appropriate because it would need to be modified most of the time.	Propose that the CM avoid to impose this checklist, instead the CM should point the topics to be addressed to describe the FC, conduct the analysis and draw the conclusion.	Requested	Not Accepted.	As mentioned in the same paragraph, the CM “provides an acceptable structured framework supporting a systematic assessment of the failure management. Alternative methods or frameworks should be agreed with the Agency.”
98	ANAC	3.1	5	“Human Factor management of failure conditions should be assessed on a per task basis, using a structured analysis model as presented in Table 1.” Although the same paragraph allows for different method to be Agreed with EASA, we believe the use of the terms “should be assessed” using the “analysis model as presented” in the quoted sentence may be misinterpreted as a requested prescriptive format, which would be more appropriate to an AMC/GM, instead of a CM.	Consider changing the quoted sentence to: “Human Factor management of failure conditions may be assessed on a per task basis, using a structured analysis model exemplified in Table 1”	Recommended	Not Accepted.	As mentioned in the same paragraph, the CM “provides an acceptable structured framework supporting a systematic assessment of the failure management. Alternative methods or frameworks should be agreed with the Agency.”
99	EMBRAER S.A.	3.1	5	It is not clear the level of granularity necessary for assessing the management of failure conditions “per task basis”.	Include examples on the level of granularity for task basis.	Recommended	Noted	EASA does not provide examples in cert memo.
100	EMBRAER S.A.	3.1 Table 1	5 7	It is not clear the moment where “5. Post failure management” starts.	Replace “5. Post failure management” by “5. Management post flight crew response”.	Recommended	Not Accepted.	EASA consider the wording “post failure” as self-explanatory.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
101	TCCA - NAC	3.1	p.6/11	<p>“Thus, the model addresses both situations, Failure Management Case #1 where explicit and unambiguous causal information is provided, Failure Management Case #2 for all other cases.”</p> <p>It is unclear whether focus would indeed be on ‘causal’ information in case #1. CAS messages are typically not about ‘cause’ (e.g. why we lost hydraulics), but rather clear indication / annunciation of the primary failure condition (we lost hydraulics), allowing the crew to provide corrective action.</p>	<p>Recommend rewording this sentence in line with contents of Table 1, i.e.</p> <p>“Thus, the model addresses both situations, Failure Management Case #1 where explicit and unambiguous <u>alert</u> pointing to the primary failure causal information is provided, and Failure Management Case #2 for all other cases.”</p>	Requested	Accepted	Text reworded accordingly.
102	TCCA - NAC	3.1	5	<p>The task analysis framework describes five phases, which all seem appropriate. However, there does not appear to be a time or phase of flight element specifically associated with these phases.</p> <p>This may be important because some failure conditions can have different stimulus and impact different functions depending on the phase of flight. Some CAS messages are inhibited for parts of takeoff, then get annunciated. Some functionality changes as the aircraft configuration changes (e.g. gear up, flaps up) which may impact the criticality of failure conditions.</p>	Suggests adding a pointer to the phase of flight and aircraft configuration when considering the other elements lists in this section.	Recommended	Noted	It is implicit that phase of flight and aircraft configurations are key elements to be considered in the human factor assessment.
103	TCCA - NAC	3.1	5	<p>Here and through a few other sections in the document the term “failure management” is used but this term is not defined in introductory section.</p> <p>Concerns, that this may cause confusion with the term “flight crew error management”.</p> <p>Failures are typically mitigated.</p>	Consider using different terminology (e.g. mitigate) or defining failure management.	Recommended	Accepted	Text reworded

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104	TCCA - NAC	3.1	5	The opening sentence of this section: “human factors management of failure conditions...” might be bit confusing.	Suggested rewording: The mitigation of failure conditions should be assessed on a per task basis for those involving human factors, using...	Recommended	Accepted	Text reworded
105	Merlin Labs	3.1	5	The phrasing in the bulleted list should match the phrasing in Table 1, column 1.	Change the wording in the bulleted list to match the wording in the first column of Table 1	Recommended	Not Accepted.	The bulleted list already follow the wording and sequence of the table 1.
106	Volocopter GmbH	3.1 ; Table 1	7	<p>“the model addresses both situations, Failure Management Case #1 where explicit and unambiguous causal information is provided, Failure Management Case #2 for all other cases.”</p> <p>Table 1 seems to make a direct link between “explicit and unambiguous” criteria and “alert pointing to the primary failure”. Although it is acknowledged that masking the primary failure could impair the understanding of the situation, the relevance of using alerts directly pointing to root causes for all cases could also be questionable. This is expected to be a case-by-case assessment, especially when introducing novel technologies.</p> <p>It seems peculiar then to directly associate the fulfillment of a HF objective to a design choice, whereas it would have been expected from the HF evaluation to precisely validate these design choices.</p>	<p>Clarify the scope for “Failure case #1” with regards to the “explicit and unambiguous” criteria of the alert.</p> <p>It is suggested to refer to AMC25.1302 which states more generally that the ““clear and unambiguous” criteria “means that [the information] can be comprehended in the context of the flight crew task and support [its] ability to carry out the intended actions (...), and to provide possible interpretations of this criteria (“primary failure”, ...) as examples only.</p>	Requested	Not Accepted	<p>Establishing if the information could be comprehended in the context of the flight crew task and support [its] ability to carry out the intended actions is the aim of the requested analysis.</p> <p>EASA strongly believe that either there is an explicit alert from the Crew Alerting System (CAS) unambiguously pointing to the initial failure and therefore the situation belongs to failure case #1, either it does not and therefore information needs to be gathered and analysed as per CM proposed framework.</p>

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107	General Aviation Manufacturers Association (GAMA)	3.1 3 rd paragraph	6	<p>EASA states on page 6: “For each applicable system failure condition, and based on the Agreed task analysis framework, the applicant should provide the full set of information described in Table 1.”</p> <p>Sentence starts with “for each applicable” but there is no prior discussion of applicability. Is it intended to apply for each failure condition where there is a crew action?</p>	<p>EASA to clarify if the intent is to apply for each failure condition where there is a crew action, an if it is indirectly referring to Figure 1.</p> <p>Additionally, EASA to clarify if the full set of information be kept in the SSA or in a FHA’s supplement.</p>	Requested	Accepted	Text reworded
108	Boeing	3.1 Table 1	7	<p>In the Post Failure Management field, the CM states: “What are the operational limitations to be respected due to the failure?” As phrased, scope of the term operational limitations is unclear.</p> <p>Operational limitations are contained in the Airplane Flight Manual, Quick Reference Handbook, Flight Crew Operations Manual, and on placards located in the flight deck. The limitations should be within the management of the flight crew.</p>	Boeing requests EASA to define what operational limitations are to be considered in the analysis.	Requested	Noted	Examples were added to clarify meaning of “operational limitations” .
109	Merlin Labs	3.1 Table 1	5-6 7	The model should not make distinctions between the two cases. The model should work for failure conditions which are indicated, not indicated, or a hybrid. Dividing this model between “alerted” and all other means of informing the crew may oversimplify the “alerted” case. Assuming “the crew is expected to directly go from the alert to the procedure” may miss a consideration of the condition if other effects coincide with the failure condition. However, the cases are great examples of the extremes of failure conditions which may exist.	Remove the “alerted” vs. all other conditions case considerations as part of the model and use them as examples. Make Table 1 a uniform set of considerations that can work for either scenario.	Requested	Not Accepted	EASA considers that the proposed table is a framework for analysis, it proposes information to be gathered and look at depending on the situation and is therefore voluntarily simplistic. It is up to the applicant to propose a different way to structure the information to the EASA.
110	Merlin Labs	3.1 Table 1	5-6 7	The initial step should be “Preceding Operating Conditions” to characterize what the flight crew may typically be doing immediately before the failure condition. This allows a deeper consideration of the transition actions for the flight crew	Add an initial step to document “Preceding Operating Conditions”	Requested	Not Accepted	The applicant may provide this information if he deems it useful, however EASA does not consider this information as required.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
111	Merlin Labs	3.1 Table 1 Task 1, Stimulus	5-6 7	Remove “Occurrence of Failure condition” / “Stimulus” step. Per Merlin Labs’ first comment, this consideration may cause an oversimplification of the alerted conditions.	In alignment with Merlin Labs comment 1: Remove the “Occurrence of Failure condition” / “Stimulus” step	Requested	Not Accepted	Comment not understood.
112	Gulfstream Aerospace Corporation	3.1, Paragraph 1, 1 st Bullet	5	“- occurrence of the failure condition (stimulus),” The occurrence of the failure condition may or may not be indicated (explicitly or not). Therefore, failure condition cannot always be considered a stimulus (assuming this stimulus is related to the flight crew).	Clarify only failure conditions with stimulus is part of the framework. Reword first bullet to “occurrence of the failure condition (with stimulus)”.	Requested	Not Accepted	EASA reminds that this CM applies whenever credit is sought from flight crew recognition of flight deck effects and/or flight crew actions when assessing system failure conditions. For the FC that do not have any associated flight crew recognition and flight crew action, the framework is obviously not applicable.
113	General Aviation Manufacturers Association (GAMA)	3.1, table 01	7	The wording in task analysis case #1 seems to indicate that the pilot needs to be aware or respond unambiguously, hence it is understood that only warnings, cautions and advisories shall be considered within this category (be it primary or secondary failures, if they are being alerted)	EASA to clarify the level of CAS applicable to case #1, specifically whether only warnings, cautions, and advisories should be included in this case.	Requested	Not Accepted	CM wording is purposely generic to cover both CAS messages and other crew alerting system means.
114	General Aviation Manufacturers Association (GAMA)	3.1, table 01	7	The wording suggests that the CM applies to failures which take credit for crew recognition/behaviour. It is implied that the CM does not apply to failure conditions that recognise there is crew action that could be taken, but that action does not mitigate/address the failure.	EASA to clarify the applicant does not have to demonstrate the validity of assumptions related to actions that could be taken but do not mitigate/address the failure condition.	Requested	Not Accepted	Comment not understood. However, EASA reminds that malicious actions are not intended to be covered by this CM.

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115	General Aviation Manufacturers Association (GAMA)	3.1, table 01	7	<p>The proposed CM 3.1 table 1 seems to include statements that provide ambiguous or unclear guidance when following the task analysis model.</p> <p>EASA states as a set of heterogeneous symptoms ‘observable Flight Deck effects’. These can be either direct or indirect, and there is no measurable limit indicated.</p>	EASA to expand guidance and include the type of observable flight deck effects to be listed (direct/indirect) and measurable criteria to analyse whether an effect is subject to listing. Consider providing examples for better guidance.	Requested	Not Accepted	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason EASA will not comply with the request to define more specific criteria.
116	General Aviation Manufacturers Association (GAMA)	3.1, table 01	7	EASA states in the model’s second row ‘ note: it can be a combination of both cases’.	EASA to provide examples on which cases can be an actual combination of both case#1 and case#2 failures.	Requested	Not Accepted	Combination of both cases could be understood as explicit message + cascading flight deck effects. No example is provided as EASA consider the proposed description self-explanatory.
117	General Aviation Manufacturers Association (GAMA)	3.1, table 01	7	Interpreting that the CM applies only to the FHA, it seems that many of the table 01 questions won’t be answered until the initial FHA development has been carried out (as pointed out in the 3.2 2nd paragraph)	EASA to indicate in the task model (table 01) the fact that the model shall evolve through the entire safety assessment development.	Recommended	Noted.	As mentioned in paragraph 3.2, “It is recognized that the safety assessment is an iterative process. In case the system definition is evolving, the assumptions need to be reconsidered, as well it is expected that the table 1 content evolves based on the evolving maturity of the systems. “

118	General Aviation Manufacturers Association (GAMA)	3.1, table 01	7	The proposed CM 3.1 table 1 seems to include questions that provide ambiguous or unclear guidance when following the task analysis model	<p>EASA to provide <u>additional information on the reach or intend of the following statements/questions:</u></p> <ul style="list-style-type: none"> – ‘What are the actions the flight crew is obliged to accomplish manually due to the failure?’, in particular, the scope and intent. – ‘What is the classification of the alert used to inform the crew of the failure?’, specifically, define if it’s warning/caution /advisory. – ‘What are the operational limitations to be respected due to the failure?’, especially its scope. – ‘Does the failure require immediate crew awareness/imm ediate crew response?’ in 	Requested	Not Accepted	<p>EASA does not concur with GAMA statement on the clarity of these questions. EASA believes that these questions are self-explanatory and understood by professionals of the field.</p> <ul style="list-style-type: none"> - “What are the actions the flight crew is obliged to accomplish manually due to the failure?” is intended to provide information on which action(s) will be needed to be accomplished manually after the failure (no automation). - ‘What is the classification of the alert used to inform the crew of the failure?’ Indeed as per CS25.1322, classification refers to Warning/caution/advisory. - What are the operational limitations to be respected due to the failure?’ Examples were added to clarify meaning of “operational limitations” . - Does the failure require immediate crew awareness/immediate crew response? It is purposely addressing the adequacy between classification of the alert and required crew awareness/response. - 'Comprehensive list': It is expected that applicant knows its design and installation so he can establish this comprehensive list.
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					particular, consider removing as it shows redundancy with the alert classification question. – ‘ Comprehensive list ’, specially, clarify how can the applicant can determine that a list is comprehensive. See comment #1 – definitions, for reference.			
119	AIRBUS DS	3.1, Table 1, 2. Perception - Failure CASE#1.	7	Airbus DS suggests to precise the link the question “ what is the classification of the alert used to inform the crew of the failure?” to CS & AMC 25.1322 for Failure CASE#1 in the 2. Perception.	Airbus DS suggests to add reference to CS and AMC 25.1322 : and reword as follows “What is the classification of the alert, <u>as per CS and AMC 25.1322</u> , used to inform the crew of the failure?”	Recommended	Accepted.	Text amended accordingly.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
120	AIRBUS DS	3.1, Table 1, 5. Post failure management - Failure CASE#1.	7	Airbus DS understands the sentence “ What are the actions the flight crew is obliged to accomplish manually due to the failure?” as an additional action, once the crew response, as per 4 Flight crew response has already allowed to recover a “stable” A/C situation, and if so Airbus DS suggest to precise it in the sentence.	Airbus DS suggests to reword as follows: What are the actions the flight crew is obliged to accomplish manually due to the <u>resulting</u> failure effect <u>for the rest of the flight</u> ?	Recommended	Accepted.	Text amended accordingly.
121	Gulfstream Aerospace Corporation	3.1, Table 1, Item 2. Perception	7	The perception phase is not limited to flight deck effects. As specified under Failure Case #2 symptoms, aircraft physical feedback can also be used as indication of a failure or malfunction.	Use the same wording from section 3.1: “Perception (by the flight crew of the failure indication(s))”.	Requested	Not accepted.	EASA considers flight deck effects larger than failure indications, hence table title for item #2 “2. Perception (by the flight crew of flight deck effects)” is considered appropriate.
122	Gulfstream Aerospace Corporation	3.1, Table 1, Item 5. Post failure management	7	Use of “unusual workload”, “unusual concentration” and “unusual force” throughout. Using the term “unusual workload” implies that “usual workload” is defined, however there is no definition provided, nor guidance provided for the applicant to define these terms. Additionally, unusual workload may not mean unacceptable workload levels. Similarly for “unusual concentration” and “unusual force”, excessive force or excessive concentration are regulatory terms; however, the criteria for “excessive” would need to be defined and is heavily dependent on the population the equipment is designed for.	The use of “excessive” could replace “unusual”, but it would need to be defined. It should also be clarified what assessment of workload, concentration, and flight controls forces are required, and also what criteria should be used to define those terms.	Requested	Not accepted.	EASA intent is for the applicant to report levels (concentration, force or workload) that are not usual in the operation of the aircraft. These levels will be later assessed for their acceptability (excessive, unacceptable...), nevertheless EASA is targeting a delta in workload, concentration, force compared to before failure situation.

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123	Boeing	3.1.2	5	The CM States: “Flight deck effects, tasks and relevant design and Human Factors vulnerabilities are different depending on whether the system provides explicit and unambiguous information allowing the flight crew to immediately identify the nature of the failure condition.” Boeing feels the first sentence is confusing. Is the intent to state that the Flight deck effects, tasks and relevant design and Human Factors vulnerabilities are all different from each other?	Boeing recommends that EASA rephrase this sentence to better communicate intent: Flight crew actions and Human Factors vulnerabilities depend on whether the system provides explicit and unambiguous information allowing the flight crew to immediately identify the nature of the failure condition.	Requested	Accepted	Text reworded
124	Boeing	3.1.3	6	The CM states: “For each applicable system failure condition, and based on the Agreed task analysis framework, the applicant should provide the full set of information described in Table 1.” The sentence starts with “for each applicable” but there is no prior discussion of applicability. Is it intended to apply for each failure condition where there is a crew action?	Boeing requests EASA to clarify if the applicability refers to Figure 1. If so, Boeing recommends that EASA rephrase to “For each applicable system failure condition where expected flight crew action is part of the severity determination... as described in Figure 1.”	Requested	Accepted	Text reworded
125	LGM (FDE)	3.2	8	The approach is based on the confidence degree. The appreciation of confidence degree may vary according the analysts.	Some example to illustrate various level of confidence would be adequate.	Recommended	Not accepted.	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason EASA will not comply with the request to define more specific criteria/examples.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
126	Saab AB	3.2	8	<p>The terms Validate and verify are not used as defined in the document and used inconsistently.</p> <p>Validate and verify are defined in section 1.4. The way “verify” is used in section 3.2 (page 8) is inconsistent with the definition and confusing. Assumptions are validated, not verified.</p> <p><u>Note:</u> Applies also to other occurrences in the document.</p>	<p>Change “Several means are available to demonstrate (verify) the validity of assumptions about flight crew behaviour in FHAs. Therefore, the applicant should implement a process to ensure that the assumptions about crew behaviour are properly validated and verified.”</p> <p>to</p> <p>“Several means are available to demonstrate the validity of assumptions about flight crew behaviour in FHAs. Therefore, the applicant should implement a process to ensure that the assumptions about crew behaviour are properly validated.”</p>	Recommended	Accepted	Text has been reworded.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
127	Saab AB	3.2	8	See NR 1. The terms Validate and verify are not used as defined in the document and used inconsistently. Validate and verify are defined in section 1.4. The way “verify” is used in section 3.2 (page 8) is inconsistent with the definition and confusing. Assumptions are validated, not verified.	Change” Relevant information about the means and methods selected to assess, to justify, and to verify the assumptions ..” To “Relevant information about the means and methods selected to assess, to justify, and to validate the assumptions ...”	Recommended	Accepted	Text has been reworded.
128	Saab AB	3.2	8	The meaning of the term “panel experts” may not be obvious. Does it refer to the applicants or the agencies experts? It should be clarified what the Agency definition or expectation is.	Suggest to add “panel experts” to definitions in section 1.4.	Recommended	Noted.	Text modified for previous comment as follow: “The following activities are meant to be run by a multi-disciplinary team consisting of relevant discipline representatives (e.g. Engineering, Safety, Flight Test and HF).”
129	Dassault Aviation	3.2 Figure 01	9	“..does the failure consequence takes credit..”	Reword “in the failure condition of concern, does the severity assessment takes credit from ..”	Recommended	Not accepted.	Comment not understood. The current wording is deemed clear.
130	Dassault Aviation	3.2 Figure 01	9	In the decision tree, scope of HF scrutiny should be limited to the failure conditions for which the severity is comprised between MIN and HAZ. (providing that NSE cannot implies crew recognition or action, and for CAT that crew action are not taken into credit)	Add a decision step or filter to limit the scope to MIN, MAJ and HAZ severities	Requested	Accepted	See comment #86
131	Dassault Aviation	3.2 Table 2	10	Since the level of confidence drive the level of scrutiny, it is very important to better define what makes the level of confidence. Agency should porpose applicable selection criteria based on ASD workgroup outcomes.	Define more applicable and less interpretative selection criteria	Requested	Not accepted.	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason EASA will not comply with the request to define more specific criteria/examples.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
132	Dassault Aviation	3.2 Table 2	10	Deliverable for very high level of confidence: a lighter process should be sufficient in this case, not imposing specific deliverables to justify the involvement of human factor experts. Proof of Engineering checking of the FHA should be sufficient	Precise if HF engineering checking or human factor CVE is an applicable evidence that the FHA has been reviewed and unless specifically mentioned all other non questionable flight crew assumptions are very high confidence	Requested	Noted.	Deliverables have been changed as follow: “Summary of cases characterized and stated by the review team as “very high degree of confidence”
133	Dassault Aviation	3.2 Table 2	10	For lower degree of confidence (high or all other cases) , the mean of compliance cannot always been determined in the FHA. It is up to the HF process to address the questionables crew behaviour assumptions and to determine the appropriate MoC	Remove the need to determine the approach and the Mean of Compliance at the step of the functional safety analysis	Recommended	Not accepted.	It is explicitly the intent of this CM to be able to define the methods and means that will be used to support the flight crew behaviour assumption verification. Therefore, it is considered by EASA as a mandatory outcome of the process.
134	Honeywell	3.2	10	The scenario-based approach is based on a methodology that involves a sample of various crews, who are representative of the <u>future users</u> , being exposed to realistic operational scenarios in a test bench or a simulator, or in the aircraft.	“intended users”	Requested	Accepted	Text modified with “intended users”.

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135	Boeing	3.2	8	On Page 8, the CM states “This approach should be considered during all systems certification plans and the System Safety Assessments (SSA) reviews utilizing multi-disciplinary teams (e.g. Engineering, Flight Test and HF).” The scope of this statement is unclear.	Boeing requestes EASA to confirm that the intended scope of the process is limited to the human factors aspects of the SSA. Due to the breadth of work related to SSAs, Boeing would recommend rephrasing the statement as follows: This approach should be considered during work involving human factors assumptions in systems certification plans and the System Safety Assessments (SSA) which utilize multidisciplinary teams (e.g. Engineering, Flight Test and HF).	Requested	Not accepted	This is clarified in the beginning of the section 3.2 “The applicant should describe the process used to manage the assumptions in general and consider in particular the validation and verification (as required) of the assumptions made about flight crew behaviour in safety assessments.”
136	Boeing	3.2	8	On Page 8, the CM states “The following activities are meant to be run by a multipdisciplinaty team consisting of test pilots, HF specialists, safety specialists and panel experts.” The reference to “panel experts is unclear. Also there is concern with limiting the pilots involved in activities to “test pilots”.	Boeing requests that EASA update the statement to state: “The following activities are meant to be run by the applicant’s multidisciplinary team consisting of pilots , HF specialists, safety specialists and system experts .”	Requested	Noted.	Sentence modified as follow: “The following activities are meant to be run by a multi-disciplinary team consisting of relevant discipline representatives (e.g. Engineering, Safety, Flight Test and HF).” See also comment #128

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137	Volocopter GmbH	3.2	11	<p>“the applicant should implement a process to ensure that the assumptions about crew behaviour are properly validated and verified”.</p> <p>Assumptions are not requirements, therefore they cannot be considered as “verified” with regards to the definition of “verify” provided in section 1.4 (“evaluate the implementation of requirements”). ARP4754A section 5.4.2.d in reference of this CM asks for “Management and Validation of Assumptions”, i.e. for a validation process that ensures that assumptions are explicitly stated, appropriately disseminated, and justified by supporting data.</p>	Replace the term “verified” used in several places of section 3.2 by “substantiated” or change the definition of section 1.4 with an appropriate one not mentioning “requirements”.	Requested	Accepted	Text reworded
138	Volocopter GmbH	3.2	8	It is not understood why the term “System Safety Assessment (SSA) reviews” is used	Propose to replace System Safety Assessment (SSA) by Functional Hazard Analysis (FHA) in consistency with the CM title and scope	Requested	Not accepted	The CM refers to general Safety Assessment. Particular attention is expected specially in the FHA, for those failure conditions where expected flight crew action is part of the severity determination
139	Volocopter GmbH	3.2	8	“The following activities are meant to be run by a multidisciplinary team consisting of test pilots, HF specialists, safety specialists and panel experts”	Recommend to add “and system engineers”	Recommended	Noted.	<p>Sentence modified as follow: “The following activities are meant to be run by a multi-disciplinary team consisting of relevant discipline representatives (e.g. Engineering, Safety, Flight Test and HF).”</p> <p>See also comment #128</p>

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140	Airbus	3.2	8	Table 2: if the expected crew behaviour can be predicted with a very high degree of confidence, accept that standardised filtering criteria can be used to define the severity. If these criteria cannot be applied, then provide a validation by appropriate workforce made of relevant discipline representative(s), using expert judgement.	Propose to add the following within Table 2, within the Cell located 1st line x Column "means": “Appropriate workforce made of relevant discipline representative(s). When a scenario belongs to a typical family of pilot behaviour already validated from an HF perspective, additional validation by the workforce is no longer necessary.”	Requested	Not accepted.	EASA understand that Airbus intent is to define “typical family of pilots’ behaviour”. If so, the approach should be proposed to the EASA and discussed at project level not in the CM content.

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141	Airbus	3.2	8	Table 2: for a very high degree of confidence, accept the use of acceptable filtering criteria as a basic. If not applicable, then use expert judgement with appropriate workforce made of relevant discipline representative(s).	For very high degree of confidence cases, it is expected that characterising the scenario as per Table 1 is robust enough to support the conclusion. Therefore, a single statement declaring that it fits with this category should be sufficient. If further evidence is needed, that means that the scenario should belong to one of the 2 other categories (“high degree of confidence” or “all other cases”). Therefore it is proposed to reword the expected Deliverables as: “Summary of cases characterised and stated as “very high degree of confidence””.	Requested	Accepted	Text modified accordingly.
142	FAA AIR-710	3.2	9	The paragraph between Figure 01 and Table 2 states, “The level of confidence drives the level of scrutiny”. Table 2 is subjective by the EASA personnel assigned to the applicant's program. What is the objective quantifiable data used to determine the level of scrutiny so applicants know exactly what you expect and how to show compliance?		Requested	Not Accepted	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason EASA will not comply with the request to define more specific criteria.

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143	FAA AIR-710	3.2	10	3 rd paragraph under Table 2 states: Allowing for the Agency to assess the approach, a failure condition sample selected by the applicant is to be Agreed with the EASA. The Agency reservest he right to increase its involvement in the oversight of human factors aspects. Is this statement related to 25.1309? Define “human factors aspects” in respect to FHA or SSA. EASA uses the term “human performance aspects” earlier in this CM but no where else is the term “human factors” aspects used. All terms need to be defined and used consistently.		Requested	Accepted	Text reworded
144	FAA AIR-633	3.2	8	Paragraph 4 under 3.2 – Approach should also include ASA as applicable.	Revise Paragraph 4 under 3.2 second sentence to: “This approach should be considered during all systems certification plans, Aircraft Safety Assessment (ASA) and the System Safety Assessment (SSA) reviews utilizing multi-disciplinary teams (e.g. Engineering, Flight Test and HF).	Recommended	Accepted	Text reworded
145	AIRBUS DS	3.2	8	“It is expected that any categorisation process is adequately documented and presented, and that the outputs of this process are provided to the authority.” Agency should rely on industry to do the activity. Material will be made available to the agency upon request by the Agency.	Airbus DS suggests to precise “that the outputs of this process are provided to the authority”, <u>upon Agency request.</u>	Requested	Not accepted.	This categorisation process and the associated outcomes are considered by EASA as deliverables.
146	Airbus Helicopters	3.2	8	The CM states that: “The applicant should describe the process used to [...]” Comment: The expectation is not sufficiently clear. ED-79A already request applicants to define Safety Plan in objectives 3.x, is it what is meant here or something different?	Please be more accurate on the kind of description expected	Recommended	Noted	This process of the assumption management for safety assessment might be defined in the validation or safety plan.

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147	Airbus Helicopters	3.2	8	<p>The CM states that: “Several means are available to demonstrate (verify) [..]”</p> <p>Comment: This sentence is omitting validation activity which should come before the verification when the product is available. This contradicts the sentence above “in particular the validation and verification (as required) of the assumptions [...]”</p>	<p>Highlight validation of assumption as first activity before the product is available</p> <p>The verification of assumption can only take place when the product is available.</p> <p>Both validation and verification of defined assumption on crew behaviour are necessary, therefore the “(as required)” in the first sentence should be removed and the mention “(verify)” should also be removed as both validation and verification are needed.</p>	Requested	Accepted	Text reworded
148	Airbus Helicopters	3.2	8	<p>Comment: “the level of scrutiny” sounds not applicable for such safety assumption which are expected to be validated and verified as per ED-79A objectives.</p>	<p>Remove the notion of “level of scrutiny” or clarify the need of such scrutiny with respect to the objective of validation and verification.</p>	Requested	Not accepted.	Scrutiny is used to tackle the level of investigation that would need to be used by the applicant to validate and verify the assumption.
149	Airbus Helicopters	3.2	8	<p>“The degree of confidence [...]”</p> <p>Comment: Figure 1 is introducing notion of “very high degree” and “high degree of confidence” which are not defined one against the other (high vs very high).</p>	<p>Define what is meant by “high degree of confidence” vs “very high degree” and vs “degree of confidence”.</p>	Requested	Not Accepted	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason EASA will not comply with the request to define more specific criteria.

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150	Airbus Helicopters	3.2	8	Comment: In Figure 01, the last box introduces “a full Human Factors process” What is meant by such “full Human Factors process”?	Please define “full Human Factors process” and related sub-subsequent activities with respect to 1302 expectation and validation and verification of the safety assumption made on flight crew behaviour.	Requested	Not accepted.	Full HF process implies the potential combination of Means of Compliance (MoC) and is likely to include scenario-based approach as per presented in the table 2.
151	Airbus Helicopters	3.2	9	Comment: The scenario based approach is exhaustively described in the AMC 25.1302, so a simple reference would be sufficient in the CM.	Propose to have a simple reference to the AMC 1302 in the CM.	Requested	Not accepted.	EASA considers that synthetic and useful background is provided in this paragraph, hence paragraph is kept.
152	Airbus Helicopters	3.2	9	The CM states that: “Allowing for the Agency to assess the approach, a failure condition sample selected by the applicant is to be Agreed with the EASA.” Comment: The way applicant are supposed to present the sample is not defined and not consistent with usual certification programme discussions, will it be done in the frame of Technical Familiarization? Or Certification Program discussions?	Please define the way applicants should provide such sampling.	Requested	Not accepted.	It is not scope of the cert memo to define how the applicants should present the failure condition sample. It is left to the applicant to decide how to present the failure condition sample.
153	Airbus Helicopters	3.2	9	The CM states that: “The Agency reserves the right to increase its involvement in the oversight of human factor aspects.” Comment: This contradicts the LOI principle defined in 21.B.100 and the DOA performance assessment aspects. Besides, if the LOI should be increased, this should fall on Panel 12 (Safety) aspects not on Panel 01 (Human Factors) aspects.	Please clarify the LOI impacts and the trigger for LOI increase in the Certification Program discussions.	Requested	Not accepted.	There is a consensus amongst authority that there is a need for an increase of scrutiny in the management of assumption made as part of the safety assessment process. The consideration contained in this CM do not replace nor take precedence over the LOI aspects as the Part 21.B.100.

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154	Independent Aircraft Modifier Alliance (IAMA)	3.2	9	Both Figure 01 and Table 2 within Section 3.2 provide good insight into dealing with the degree of confidence of flight crew behaviour, but the realization of the deliverables in such a way to be acceptable to EASA is missing	As the level of confidence drives the level of scrutiny, we suggest some simple use cases such to remove the high level of subjectivity which may lead to misalignment between members involved. If possible, inclusion of dealing with this CM into the EASA DOA & Certification Workshop Conference would be appreciated, i.e. similar to that on CM S-013 in the 2021 Workshop.	Requested	Noted	EASA will consider to reserve one slot in one of the EASA events to present the cert memo. In addition the industry standardisation bodies such as SAE S18H and EUROCAE WG63H are playing an important role in standardisation and sharing of good practices across the industry.
155	ENAC Ente Nazionale Aviazione Civile Italian Civil Aviation Authority	3.2	10	As shown by the service experience, the inability of the flight crew to sustain unusual and prolonged efforts on flight controls may undermine the successful outcome of a post failure management. In this respect it is proposed to add some considerations on the selection of crews used for the assessment campaign who should be sufficiently representative to cover the range in terms of physical size and strength of the crews expected to operate the aeroplane in service.	To add the following text : For those scenarios for which unusual physical efforts in terms of duration and/or magnitude is expected for post failure management, the physical size and strength of crews used for the assessments should be sufficiently representative to cover the reasonable range of size and strength of crews who may operate the aeroplane in service.	Recommended	Partially Accepted.	EASA believe that addition of “- Is unusual workload concentration and force required as part of the flight crew response ?” is covering the concern expressed by ENAC. The criteria for selecting the crews used for the assessments will be addressed at test plan level.

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156	Bombardier	3.2	8	<p>“The applicant should describe the process used to manage the assumptions in general and consider in particular the validation and verification (as required) of the assumptions made about flight crew behaviour in safety assessments.”</p> <p>Validation and verification processes apply to requirements and not to assumptions. While assumptions may justify and provide rationale for requirements, they are not by themselves requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified).</p> <p>The use of “safety assessments” in the sentence above could have different interpretations. This proposed Certification Memorandum addressed the Functional Hazard Assessment, so the sentence could refer to FHAs instead of safety assessments.</p>	Change sentence to state “(...) the process used to manage the assumptions in general and consider in particular the confirmation of the assumptions made about flight crew behaviour in functional hazard assessments.”	Requested	Accepted	Text reworded
157	Bombardier	3.2	8	<p>“Several means are available to demonstrate (verify) the validity of assumptions about flight crew behaviour in FHAs. Therefore, the applicant should implement a process to ensure that the assumptions about crew behaviour are properly validated and verified.”</p> <p>Validation and verification processes apply to requirements and not to assumptions. While assumptions may justify and provide rationale for requirements, they are not by themselves requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified).</p>	Change sentences to state: “Several means are available to confirm the validity of assumptions about flight crew behaviour in FHAs. Therefore, the applicant should implement a process to ensure that the assumptions about crew behaviour are properly confirmed.”	Requested	Accepted	Text reworded

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158	Bombardier	3.2	8	<p>“The process should describe the level of scrutiny to be applied when validating and verifying an assumption, as well as the criteria used for its establishment.”</p> <p>Validation and verification processes apply to requirements and not to assumptions. While assumptions may justify and provide rationale for requirements, they are not by themselves requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified).</p>	Change sentence to state “(...) when confirming an assumption, (...)”.	Requested	Accepted	Text reworded
159	Bombardier	3.2	8	<p>“This approach should be considered during all systems certification plans and the System Safety Assessment (SSA) reviews utilizing multi-disciplinary teams (e.g. Engineering, Flight Test and HF).”</p> <p>The intent of this sentence is not clear. The FHA process does already include several multi-disciplinary reviews with Engineering, Flight Test, Human Factors and other disciplines, to discuss failure recognition by the crew and crew actions. When agreeing that subsequent HF analysis or test is required, the goal is ultimately just to ensure that a failure condition can have its effects and classification re-assessed in case the HF activities conclude that the expected crew behaviour is unreasonable based on human performance aspects.</p>	<p>Remove sentence, or change it to clarify high level goal of managing and confirming these assumptions.</p> <p>“Certification plans should reflect this approach and define the means to ensure a failure condition has its effects and classification re-assessed in case HF activities determine that the expected crew behaviour is unreasonable based on human performance aspects.”</p>	Requested	Partially accepted	EASA agrees with the comment, nevertheless it leaves the applicant to decide in which document the approach should be reflected.

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160	Bombardier	3.2	8	<p>“Relevant information about the means and methods selected to assess, to justify, and to verify the assumptions about flight crew behaviours, for each applicable system failure condition should be included and documented.”</p> <p>Validation and verification processes apply to requirements and not to assumptions. While assumptions may justify and provide rationale for requirements, they are not by themselves requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified).</p> <p>The sentence is not clear about what “to justify an assumption” means. Assessing the assumption involves reviewing it and establishing a level of scrutiny, while confirming the assumption involves providing supporting data in accordance with the level of scrutiny.</p>	Change sentence to state “(...) to assess and to confirm the assumptions about flight crew behaviours (...)”.	Requested	Accepted	Text reworded
161	Bombardier	3.2	10	<p>“Scenario” and “Operational Scenario”</p> <p>Scenario based might not always be the optimum approach due to the potentially long test duration and the difficulty of performing multiple repetition in a rigid scenario framework (which will yield less data points). In some cases such as for pure reaction time, a part task human in the loop approach with multiple runs per subjects might provide better results to establish realistic assumptions. A broader perspective than only scenario based assessment should be included in the CM to cover these cases.</p>	Rephrase by extending the scope to other “Human in the Loop” testing when “Scenario” or “Operational Scenario” are mentioned.	Requested	Noted.	EASA shares Bombardier’s opinion and believe the current wording “Complex tools and methods (test bench, simulator, aircraft, scenario-based approach) in addition to analysis and engineering judgement.” are appropriately addressing Bombardier expressed concern.
162	Bombardier	3.2	10	<p>“a sample of various crews, who are representative of the future users”</p> <p>The sentence is not clear and may be interpreted as requiring final end user participation. Final end users proficient on the product are only available late in a project and would not be available for timely confirmation of assumptions.</p>	Rephrase by “a sample of various crew including crews not involved in the project”	Requested	Noted.	Text modified with “intended users”.

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163	Bombardier	3.2	10	<p>“To avoid an obvious risk of experimental bias, the crew participating in the assessment should not be briefed in advance about the details of the failures and events to be simulated.”</p> <p>Considering that only results from a naïve crew first exposure to a particular situation are acceptable would limit the amount of potential data points that can be gathered from multiple runs from the same crew (where the crew would be considered as briefed” after the first run). Tests and evaluations should be performed according to human factors best practices but need to consider that not all tests and evaluations will conform to a unique model.</p>	Add “for tests that warrant a naïve user”	Requested	Noted.	EASA concur with Bombardier stating that “Tests and evaluations should be performed according to human factors best practices”, EASA considers that the quoted sentence is part of these best practices and include the use of naïve users when needed
164	ANAC	3.2	8	<p>Section 3.2 lists the elements that should be identified and documented in the process. When “the available means” is mentioned, it would be beneficial to also mention its representativeness for the assessment to be performed.</p>	<p>Suggest expanding the guidance so that representativeness for the assessment is highlighted as one important aspect to be considered in defining the “available means”.</p> <p>OR</p> <p>In order to highlight the necessity to address representativeness, this excerpt could be revised to “available means and their limitations”.</p>	Recommended	Not Accepted.	EASA acknowledge the ANAC comment and agree with the concern. However, the “validity” of the test means is handled in specific certification material (i.e. CRI related to test articles and test plans).
165	EMBRAER S.A.	3.2	9	<p>The text “The level of confidence drives the level of scrutiny.”. However, AMC 25.1302 also contains criteria for defining level of scrutiny during the certification process. Instead of defining a new criteria for driving the level of scrutiny for assumptions validation based on confidence degree, use the existing criteria on AMC 25.1302.</p>	Reference the criteria on AMC 25.1302 for defining the level of scrutiny for assumptions validation.	Recommended	Not accepted.	See EASA response to comment See comment #20.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
166	TCCA - NAC	3.2	p.8/11	For clarity and to more explicitly address the contents of this section, it is recommend changing the title of section 3.2 to “Process for management of crew behaviour assumptions” or something similar. The current title, “Process considerations” would seem vague and not sufficiently descriptive.	As noted in comment.	Requested	Not Accepted	Section is also addressing other aspects like agency involvement, documentation,... This generic title is deemed to be more adequate
167	TCCA - NAC	3.2	p.8/11	The following wording updates to section 3.2 are recommended to improve clarity and precision of the guidance: “ <u>The applicant should define and document</u> describe the process used to manage...” “...the available <u>testing environments</u> means (engineering benches, ...” “...the <u>possible validation</u> methods used (engineering judgement, ...” “...the criteria used to decide what are the most suitable means and methods to <u>validate</u> address the <u>crew behaviour assumptions supporting the HF considerations of FHAs.</u> ” “ <u>The process should also describe the criteria to be used when determining the level of scrutiny to be applied for</u> when validating and verifying an assumption, as well as the criteria used for its establishment. ”	As noted in comment.	Requested	Accepted	Text reworded
168	TCCA - NAC	3.2	p.8/11	“This approach should be considered during all systems certification plans and the System Safety Assessment (SSA) reviews utilizing multi-disciplinary teams (e.g. Engineering, Flight Test and HF).” This sentence looks out of place, and to some extent redundant. Section 3.2 already indicates how the validation of assumptions relates to the safety assessment process, and already refers to the multidisciplinary team in the last sentence at the bottom of p.8. Also the reference to Cert Plans is not understood; this is related to validation activities supporting the FHA.	Recommend deleting the sentence quoted.	Requested	Partially accepted	The sentence highlights the importance to have a multi-disciplinary team, that is a key element for the assumptions validation activities. Reference to the certification plan is removed.

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169	TCCA - NAC	3.2	p.8/11 p.10/11	<p>“Relevant information about the means and methods selected to assess, to justify, and to verify the assumptions about flight crew behaviours, for each applicable system failure condition should be included and documented.”</p> <p>While fully agreeing with the intent of this sentence, this would not belong to the process definition (i.e. section 3.2) but rather process outputs, i.e. documentation of the proposed validation means and methods for each crew behaviour assumptions in support of FHAs.</p> <p>Process outputs would usually be recorded outside of the document defining process.</p> <p>Similarly the last two paragraphs of section 3.2, on p.10, would relate to the process outputs and would be best documented in a separate section.</p>	Recommended to move the quoted sentence to a new section addressing documentation of V&V means for assumptions (i.e. new section on outputs of the process, vs 3.2 defining the process itself), along with similar contents such as the last two paragraphs of section 3.2, which address results of the assumptions V&V activities.	Requested	Noted	The section is generic addressing all process considerations (see also comment #166)
170	TCCA - NAC	3.2	p.8/11	<p>“It is expected that any categorisation process is adequately documented...”</p> <p>Unclear what ‘categorization’ refers to here. Is it referring to the level of scrutiny? Degree of confidence? Both? The two concepts would be linked to some extent, but the nature of the assumption and complexity of the failure scenario would also play in role in determining the extent and scope of validation activities. See also comment below on Fig. 1 and Table 2.</p>	Please clarify the intent per comment, and update the text as necessary. Use of consistent terminology between the various parts of the document will help ensure clear understanding.	Requested	Accepted	Text reworded.

171	TCCA - NAC	3.2 Fig. 1 Table 2	p.9- 10/11	<p>“EASA considers that the process presented in figure 01 provides an acceptable approach.”</p> <p>The contents of Figure 1 and Table 2, linking degree of confidence in the flight crew behaviour assumption and level of scrutiny isn’t sufficiently explained or described at the moment, and could in all likelihood result in quite different interpretations.</p> <p>Some observations and questions:</p> <p>1- These figure / table are not really presenting a ‘process’, but simply high level guidelines on the inverse relationship between degree of confidence and level of scrutiny. While agreeing with this basic principle, this will need elaboration to ensure consistent interpretation.</p> <p>2 - How would one characterize or delineate between “very high level of confidence” and “high level of confidence”? As proposed this would be an important distinction as it determines whether supporting data is required for the validation of assumptions.</p> <p>3- No link or reference to Case #1 vs Case #2 from Table 1? Wouldn’t this delineation (i.e. clear single CAS message, vs all other cases) play a role in the degree of confidence and corresponding level of scrutiny?</p> <p>4- Who would make the determination of the ‘degree of confidence’ in the assumptions? If this determination is not done by the appropriate specialists / team in the first place, the rest of the exercise could be of questionable value. Section 1.4 indicates this is done by a ‘review team’; same as the ‘team’ / ‘multidisciplinary team’ referred to in Fig. 1? This should be clarified in section 3.2.</p> <p>5- Is there an intended difference between a “team made of relevant disciplines representatives” and a “multidisciplinary team”? These would seem to be the same, and if so the same term should be used to avoid confusion. If different, should be further elaborated to clarify.</p> <p>6- Terminology and contents between Fig 1 and Table 2 isn’t aligned in all cases. E.g. ‘expert judgement’ vs ‘team of representatives from relevant disciplines’ vs ‘multidisciplinary team’.</p> <p>7- Table 2: The means and deliverables for the 2nd and 3rd rows of the table (‘high degree of confidence’ and ‘other cases’) should presumably also include the contents of the</p>	Additional elaboration and clarifications needed, per comments and questions noted, to ensure clarity and consistent interpretation.	Requested	<p>1- Noted</p> <p>2- Not accepted.</p> <p>3- Not accepted</p> <p>4- Not accepted</p> <p>5- Accepted</p> <p>6- Accepted</p> <p>7- Not accepted.</p>	<p>1- The whole paragraph 3.2 is intended to present a process. The figure 1 and table 2 are considered parts of this process.</p> <p>2- It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own criteria on confidence degree.</p> <p>3- Although it is likely that case #1 would lead to high degree of confidence. EASA considers there is no systematic relation between described cases #1 and #2 and the degree of confidence. Hence no association of these concepts is made in the document.</p> <p>4- As mentioned in the paragraph 3.2, the described activities are meant to be run by a multidisciplinary team consisting of test pilots, HF, safety and panel systems experts.</p> <p>5- Text amended accordingly.</p> <p>6- Covered by bullet 5-</p> <p>7- EASA does not consider means and deliverables presented in table 2 lines 2 and 3 as required for line 4.</p>
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NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
				above rows. For example ‘appropriate team’ and ‘summary of cases’ would also need to be provided for cases other than ‘very high degree of confidence’.				
172	Collins Avionics	3.2	8	Third paragraph uses three methods to state a single means to ensure an assumption is correct and complete. It states, “...are available to demonstrate (verify) the validity....”. “Demonstration” is a type of verification method, at least in ED79A/ARP4754A.	“Several means are available to verify and/or validate assumptions about flight crew...”	Recommended	Accepted	Text reworded
173	Collins Avionics	3.2	8	Third paragraph, first bullet, “the available means” is not clear. Available means of what?	“the available verification/validation environments”	Recommended	Accepted	Text reworded
174	Collins Avionics	3.2	8	The Process Consideration discussion mentions both validation and verification aspect of the FHA assumptions together. This makes it unclear to which portions of the guidance are intended as an element of assumption validation versus assumption verification. It appears that “the “Confidence Degree” is used as a component of validation while the “Level of scrutiny” as utilized is an aspect of assumption verification. It should be made clear if the definition of “level of scrutiny” here is the same as CS 25.1302.	Suggest splitting the process considerations to discuss assumption validation then verification which can be better mapped to a development cycle. Provide a definition for Level of Scrutiny	Requested	Not accepted.	In accordance with the draft ARP4754B, the term “confirmation” has been used for assumptions. See EASA response to comment See comment #20.

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175	Collins Avionics	3.2	8	<p>1st paragraph, “(as required)”: Where is it acceptable to not verify an assumption made about the flight crews interaction with a system failure?</p> <p>It is unclear what the expectation for where the “as required” is from, is this definition from EASA or is the expectation that the applicant’s process needs to describe this?</p>	<p>Suggest removing “(as required)” from the 1st paragraph or otherwise outline those cases the verification of FHA related assumptions is required/not required.</p> <p>Should this instead indicate that the applicant’s process should describe under what conditions an FHA assumption requires/does not require verification?</p> <p>The question as it pertains to FHA assumption verification similarly applies to the discussions after Figure 1 where the text describes assumption validity when demonstrating the assumption has been verified may be expected to confirm that the effects/severity described by the FHA are accurate.</p>	Requested	Noted	Text reworded
176	Collins Avionics	3.2	8	<p>Paragraph 3 states this approach should be considered as part of the SSA reviews, but no clarification or guidance is provided on how this should be accomplished.</p>	<p>Clarify the role of the SSA in the scope of this memo or remove mention of this as part of the SSA process.</p>	Requested	Not accepted	The process to manage assumption made about flight crew behaviours in the safety assessment is part of the SSA review scope.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
177	Collins Avionics	3.2	10	Paragraph proceeding Table 2, states “sample of various crews”, and” ...varies from three to five...”. It is increasingly difficult to find a diverse pilot population base that meet the Certification Authority’s expectations and including the number of flight crew required to serve in these types of tests. More is needed to better scope/bind what are the minimum participants and participant characteristics of the pilot population base to be considered (line pilots versus flight test pilots, male, female, height, etc). Having a more defined criteria would help to ensure that the pilot participants fall within a clear set of expectations.	Provide more guidance on pilot participant characteristics and the criteria for the number of flight crew required to comply with this guidance. Is this an aspect the agency expects to be specified and Agreed upon as part of the plan for compliance to 25.1302 or to AC 25.1523. The questions of this comment may be coupled with those questions posed in Comment 1 above.	Requested	Noted.	As quoted in the CM §3.2, more detailed guidance on Human Factors best practices (participants characteristics, number of participants) can be found in the AMC25.1302. In order to avoid duplication, only reference is made in this CM. As mentioned in paragraphs 1.1 and 2.1, the associated regulatory requirement is the CS25.1309(c) and (d). Hence EASA expects applicants to address the elements presented in this CM in the compliance documentation associated to CS25.1309. However, it is also acceptable to address the HF specific strategy/aspects as part of the HF documentation.
178	Collins Avionics	3.2	10	Second paragraph proceeding Table 2, states “The applicant may be requested to provide...”. This seems to contradict the third paragraph in 3.2, where it states, “At least the following elements should be identified and documented...”	“The applicant should provide the relevant...”	Recommended	Not Accepted	The third paragraph in 3.2. refers to the applicant documentation, the second paragraph below table 2 refers to the deliverable to the authority.
179	Collins Avionics	3.2	10	Last paragraph, states “The Agency reserves the right to increase its involvement in the oversight of human factors aspects.” It is Collins understanding that CS 25.1302 is not a regulation that is delegated. Seems like the wording should tie in the same expectations as CS-25 Amdt 27 Subpart F AMC 25.1302, chapter 4 (Certification Planning). .	“Applicants can gain significant advantages by involving the Agency in the earliest possible phases of application and design. This will enable timely agreements on potential design related human factors issues to be reached and thereby reduce the applicant’s risk of investing in design features that may not be acceptable to the Agency.”	Recommended	Not accepted.	The exact intent of the comment is not clear to EASA. It is reminded that as mentioned in paragraphs 1.1 and 2.1, the CM associated regulatory requirement is the CS25.1309(c) and (d), not CS25.1302. Hence, and although Collins understanding is correct, wording is not required to tie the same expectations as for CS25.1302.

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180	ASD	3.2	7	The CM uses alternatively “degree of predictability” and “confidence degree”. We are missing a definition of these notions. In the last update “Degree of predictability” was removed. Definition provided for “Confidence Degree” added as below: Confidence degree: Perceived validity of the assumption from the review team based on the plausibility of the described expected crew behaviour.	Confidence degree: With respect to Table 2 "Recommended deliverables", the degree (very high, high, other) mirroring how confident or certain the applicant can be, based on expert judgement, that flight crew behaviour assumptions taken in aircraft and system FHAs are representative of the concerned flight crew population capabilities. Note that flight crew behaviour stands in that context as flight crew ability to recognize, interpret and respond to the situation.	Requested	Not accepted.	EASA considers that the current definition of Confidence degree is correct and appropriately reflect EASA’s intention.
181	General Aviation Manufacturers Association (GAMA)	3.2 1 st paragraph 3.2 4th paragraph	8	CM’s applicability is not clear between crew assumptions made in FHAs and crew assumptions in the context of a SSAs.	EASA to provide clarity that CM is only applicable to crew assumptions made in FHAs only.	Requested	Noted	This Certification Memorandum (CM) aims at stressing the importance of considering the Human Factors in Aircraft and System Safety Assessments for Large Aeroplanes, especially in the classification of Failure Condition in the Aircraft and System Functional Hazard Assessments (FHA).

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
182	Boeing	3.2 below Table 2	10	Boeing believes the Implication that simulation using representatives who are “representative of future users” is unrealistic.	Boeing would like to note that the test pilot community is trained to assess failure conditions with a mindset of representing operational pilot population. Boeing requests that EASA remove the implication that a sample population must be used.	Requested	Noted	EASA do not disagree on the use of test pilots for the assessments. The fact that they are instructed to behave as operational crews make them representative of the final intended users.
183	ADSE B.V. The Netherlands	3.2 Process Considerations	8	<p>It would be best to emphasize the use of the five phases of the task analysis model (described in paragraph 3.1 and table 1) in the SSA itself. In that way, the intermingling of the different points of view are minimized and can be analysed separately.</p> <p>As an example, item 4 (flight crew response) can be compared with the effect on the flight crew in AMC 25.1309 (figure 2a in AMC 25.1309) and should give an indication that the correct classification of the failure condition is selected.</p>		Recommended	Accepted	It is specified in section 3.2 “This approach should be considered during all systems certification plans and the Aircraft and System Safety Assessment (SSA) reviews [...]”

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184	UK CAA	3.2 Process Considerations Table 2	8, 10	<p>The CM provides a clear, incremental and proportional approach to assessing and validating the Human Factors elements of FHA, which the CAA welcomes and supports.</p> <p>However, whilst the CM does imply the importance of including pilots from different backgrounds and levels of experience, through the use of the phrase “various crews, who are representative of the future users” (Page 10, first paragraph), the CAA does not feel the CM addresses adequately the risks associated with company test pilots playing too large a role in these types of assessment, due to their closeness to the development and certification flight test programme and their deep familiarity with the aeroplane.</p> <p>To ensure the validity of such assessments the CAA believes it is essential they include inexperienced pilots, and also experienced pilots who do not have type ratings for similar types.</p>	<p>The CAA requests that EASA strengthens the requirements of Section 3.2 of the CM to ensure that applicants cannot rely too heavily on company test pilots during Human Factors assessments, up to and including assessments in Table 2 that have a “high degree of confidence”.</p> <p>The CAA requests also that EASA considers specifically requiring applicants to show, for cases where there is a high degree of confidence or less, that they have included in the analysis / assessment both an inexperienced pilot and an experienced pilot who does not hold a type rating on a similar type produced by the applicant. Whilst this requirement would slightly increase the burden on the applicant, the CAA believes it would be proportionate to do so.</p>	Requested	Not accepted.	The question of the representativeness of the crews used for the assessments is dealt with at project level. A various range of crews may be used, including test pilots from the applicant or actual operational crews. In case test pilots from the applicant are used they have to be briefed prior to the assessment on the expectation that they should behave as operational crews.

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185	UK CAA	3.2 Process Considerations	8/11	<p>The flight test pilot evaluation should take into account the variability of flight crew behaviour and skills as it impacts the perception, processing and response of the flight crew.</p> <p>Objective: increase the degree of confidence in the flight crew behaviour assumption.</p>	<p>The UK CAA requests EASA to add the following to para. 3.2 Process Considerations:</p> <p>The flight test pilot evaluation should take into account the variability of flight crew behaviour and skills such as, but not limited to:</p> <ul style="list-style-type: none"> - Effect of low experienced pilot (e.g. MPL pilot) - Effect of reduced currency (e.g. ULH operation with pilot performing less than 10 landings per year or less than 1 hr of manual handling per year). <p>Effect of fatigue (reduction in cognitive skills) applicable to flight crew schedule operating such aircraft only just within EASA ORO.FTL limitation.</p>	Requested	Partially accepted	EASA agree that the comment is valid and that due consideration should be given to crew profiles. However, it is not deemed adequate to mention it at the CM level, as the question is project specific and is therefore expected to be addressed in the test plans.

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186	UK CAA	3.2 Process Considerations	8/11	<p>If specific flight crew behaviour or experience assumptions are made, such assumptions should be clearly disclosed to the Panel 2 evaluation team to support the validation of the Pre-requisites for Initial Type Rating & Checking and Training and Areas of Special Emphasis (TASE) proposed by the aircraft TC holder. (GM1 FCD-100)</p> <p>Example: If the flight behaviour is based on a 1,500hr pilot with 1,000hrs of CS-25 type time, such assumption should also be made to the pre-requisites for initial Type rating course.</p> <p>Example: if specific flight crew perception and processing of failure indication are made, specific TASE could be raised to increase the degree of confidence in flight crew response.</p>	<p>3.2 Process Considerations: currently states: Relevant information about the means and methods selected to assess, to justify, and to verify the assumptions about flight crew behaviours, for each applicable system failure condition should be included and documented.</p> <p>The UK CAA requests EASA to add the following:</p> <p>Such information should also be made available to the Panel 2 team during the OSD-FCD evaluation to support the validation of the Pre-requisites for Initial Type Rating & Checking and Training and Areas of Special Emphasis (TASE) proposed by the aircraft TC holder. (GM1 FCD-100).</p>	Requested	Not accepted.	Although comment is valid, this is out of scope for the CS 25.1309 safety activities, in specific for the validation of flight crew behaviour assumptions.
187	General Aviation Manufacturers Association (GAMA)	3.2, Page 10, Para 1	10	The proposed language ‘representatives of future users’ does not reflect on current manufacturer’s capability to use trained test pilots with an expertise in line with that of the existing pilot community	EASA to remove ‘representatives of future users’	Recommended	Not accepted.	The question of the representativeness of the crews used for the assessments is dealt with at project level. A various range of crews may be used, including test pilots from the applicant or actual operational crews.

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188	Gulfstream Aerospace Corporation	3.2, Paragraph 1	8	Section 1.4 defines “verify” as an act to evaluate the implementation of requirements, not assumptions. This definition is aligned with EUROCAE ED-79 / SAE ARP 4754. Validation, on the other hand, is applicable to both requirements and assumptions, since the objective is to determine their correctness and completeness.	Remove “and verification (as required)” from this sentence OR reword this sentence to “The applicant should [...] the validation of the assumptions and, as required, the verification of their associated requirements made about flight crew [...]”.	Requested	Accepted	Text reworded
189	Gulfstream Aerospace Corporation	3.2, Paragraph 3, Sentence 1	8	“Several means are available to demonstrate (verify) the validity of assumptions about flight crew behaviours in FHAs.” The objective of the verification, as defined in Section 1.4, is not to demonstrate the validity of requirements (or assumptions for that matter). The requirement (or assumption) justification, review, test, etc. demonstrate its validity.	Reword this sentence to read “Several means are available to validate the assumption about [...]”.	Requested	Accepted	Text reworded
190	Gulfstream Aerospace Corporation	3.2, Paragraph 3, Sentence 2	8	“Therefore, the applicant should implement a process to ensure that the assumptions about crew behaviour are properly validated and verified.” Assumption can be a source for creating requirements. These requirements are used to define the aircraft/system architecture. The verification activity is needed to demonstrate the architecture meets the requirements. Therefore, there is no verification activity directly associated to assumptions.	Remove “and verified” from this sentence.	Requested	Accepted	Text reworded

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
191	Gulfstream Aerospace Corporation	3.2, Paragraph 4, Sentence 1	8	<p>“The process should describe the level of scrutiny to be applied when validating and verifying an assumption, as well as the criteria used for its establishment.”</p> <p>Assumption can be a source for creating requirements. These requirements are used to define the aircraft/system architecture. The verification activity is needed to demonstrate the architecture meets the requirements. Therefore, there is no verification activity directly associated to assumptions.</p>	Remove “and verifying” from this sentence.	Requested	Accepted	Text reworded
192	Gulfstream Aerospace Corporation	3.2, Paragraph 5	8	<p>“Relevant information about the means and methods selected to assess, to justify, and to verify the assumptions about flight crew behaviours, for each applicable system failure condition should be included and documented.”</p> <p>Assumption can be a source for creating requirements. These requirements are used to define the aircraft/system architecture. The verification activity is needed to demonstrate the architecture meets the requirements. Therefore, there is no verification activity directly associated to assumptions.</p>	Replace “to verify” with “to validate”.	Requested	Accepted	Text reworded
193	Boeing	3.2, Table 2	10	<p>Boeing uses the term “deliverable” in reference to formal Certification Plan deliverables for compliance, it is unclear the intent of the term in this regards to this CM. Boeing views the human factors analyses as supporting information to the Systems Safety Assessments.</p>	<p>Boeing requests that EASA add the definition for “Deliverable” in the context of this Certification Memorandum to Section 1.4: Definitions.</p>	Requested	Not accepted.	In EASA system, the classification of certification document and the related EASA involvement is handled under the Level of Involvement. LoI is managed at project level, and CM should be kept at high level. Therefore, the mentioned deliverables could have different classification, definition is hence difficult at CM level.

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194	AIRBUS DS	3.2, table 2	8	Airbus DS suggest to remove the word “included” in the sentence “Relevant information about the means and methods selected to assess, to justify, and to verify the assumptions about flight crew behaviours, for each applicable system failure condition should be included and documented.” as no specific related document is mentioned	Airbus DS suggests to reword as follows “Relevant information about the means and methods selected to assess, to justify, and to verify the assumptions about flight crew behaviours, for each applicable system failure condition should be documented.”	Recommended	Accepted	Text reworded

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195	AIRBUS DS	3.2, table 2	10	<p>In the table2, in line with Airbus DS comment#4, Airbus DS suggests to gather the “evidences” in a traceability matrix (available upon Agency request), rather than making all evidences as certification deliverables. The evidences will be based on</p> <ul style="list-style-type: none"> - expert judgement description (for very high degree of confidence) - expert judgement supported by additional internal data analyses or review reports reference (for high degree of confidence) - certification test plans and reports (for all other cases) <p>Airbus DS suggest not to consider all outputs as certification deliverables.</p>	<p>In the table 2, Airbus DS suggests to change “deliverables” by “evidences”.</p> <p>And to replace</p> <ul style="list-style-type: none"> - “summary of cases supported by applicable evidence” by “expert judgement description” (for very high degree of confidence) - “analyses or review reports” by “expert judgement supported by additional data analyses or review reports reference” (for high degree of confidence) - “test plans and reports” by “certification test plans and reports references” (for all other cases). <p>Considering that certification test plans and reports will be delivered in the certification dossier.</p>	Requested	Noted	The way how to gather evidence can be discussed during programme certification activities.

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196	Boeing	3.2.1	8	The CM states “The applicant should describe the process used to manage the assumptions in general and consider in particular the validation and verification (as required) of the assumptions made about flight crew behaviour in safety assessments.” Boeing would like to understand what was intended to be covered by “verification”. Boeing would like to note that the definition of verification in the Definition Table is not applied consistently throughout the document.	Boeing requests EASA to provide clarification in the text of CM. Please clarify if verifying the crew procedure is correct, that flight deck designs as implemented allow for crew actions, or if something else was intended.	Requested	Accepted	Text has been corrected
197	Boeing	3.2.1, 3.2.4	8	In other places of the document it is clear that the applicability is just for FHAs, but in this section the CM references safety assessments.	Boeing requests that EASA provide clarification on the CM applicability to crew assumptions made in FHAs only.	Requested	Noted	This Certification Memorandum (CM) aims at stressing the importance of considering the Human Factors in Aircraft and System Safety Assessments for Large Aeroplanes, especially in the classification of Failure Condition in the Aircraft and System Functional Hazard Assessments (FHA).
198	LGM (FDE)	3.3	10	The traceability is expected to be provided in an aircraft-level document. Is the traceability can be provided up to a training pedagogic design document ?	It is proposed to open the traceability expectation to other mean than aircraft-level documents.	Recommended	Noted	It is not clear which document is referred by this comment. A process must is to be defined and documented to confirm the assumptions and ensure traceability to the supporting evidences.
199	Saab AB	3.3	10	“... will be used to ensure the traceability of assumptions (to an AFM procedure for instance) ...” This section could be interpreted as there is an expectation that it should be possible to backtrace a procedure from an aircraft manual to an assumption.	Suggest to remove (to an AFM procedure for instance).	Recommended	Noted	It is not expected to backtrace a procedure from an aircraft manual to an assumption.

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200	Boeing	3.3	10	On page 10, the CM states “A process must be defined to validate these assumptions. The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.” Boeing believes the contents and scope of an “aircraft-level document” is unclear.	Boeing request that EASA provide an example of an aircraft-level document and/or expected contents of such a document.	Requested	Not accepted.	It is not scope of the cert memo to describe of the content of the aircraft level document. It is left to the applicant to provide a proposal.
201	Boeing	3.3	10	The CM states: “The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.”	Boeing requests that EASA break this section into two sentences: “The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance). In the System Safety Assessments, provide a statement that all assumptions have been validated and/or verified.”	Requested	Not accepted	The statement is deemed to be clear

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202	Boeing	3.3	10	For smaller change projects, does the process need to document at the airplane level (assuming this means an SPP type document)?	Boeing request that EASA add clarification on the types of documentation that can be used to contain the process description.	Requested	Noted	As per section 4, “...The guidance in this Certification Memorandum affects applicants showing compliance with CS 25.1309 and CS 25.1302 for certification of a new type design, significant major changes (or STCs) to a type design or any major change that introduces new failure conditions or significantly affects existing failure conditions (change in cockpit effects or in assumed pilot reaction) on Large Aeroplanes. The application will be discussed on project level on a case-by-case basis.”
203	FAA AIR-633	3.3	10	“The expected flight crew behaviour must be documented as an assumption as part of the safety assessment process.” the above sentence to replace safety assessment process term with FHA since FHA is discussed earlier	“The expected flight crew behaviour must be documented as an assumption as part of the FHA.”	Recommended	Not accepted	This Certification Memorandum (CM) aims at stressing the importance of considering the Human Factors in Aircraft and System Safety Assessments for Large Aeroplanes, especially in the classification of Failure Condition in the Aircraft and System Functional Hazard Assessments (FHA).
204	FAA AIR-633	3.3	10	“...and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.” the above sentence to replace safety assessment process term with FHA	“...and provide a statement that all assumptions have been validated and/or verified prior to submit the final FHA.”	Recommended	Not accepted	This Certification Memorandum (CM) aims at stressing the importance of considering the Human Factors in Aircraft and System Safety Assessments for Large Aeroplanes, especially in the classification of Failure Condition in the Aircraft and System Functional Hazard Assessments (FHA).
205	Bombardier	3.3	10	“A process must be defined to validate these assumptions.” Validation and verification processes apply to requirements and not to assumptions. While assumptions may justify and provide rationale for requirements, they are not by themselves requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified).	Change sentence to state “(...) to confirm these assumptions”.	Requested	Accepted	Text reworded accordingly.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
206	Bombardier	3.3	10	<p>“The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.”</p> <p>Validation and verification processes apply to requirements and not to assumptions. While assumptions may justify and provide rationale for requirements, they are not by themselves requirements. The current drafts of industry guidance documents SAE ARP 4754-B / EUROCAE ED-79B and SAE ARP 4761-A / EUROCAE ED-135 are consistent in stating that assumptions should be confirmed by supporting data (as opposed to validated or verified).</p>	Change sentence to state “(...) that all assumptions have been confirmed prior to (...)”.	Requested	Accepted	Text reworded accordingly.
207	ANAC	3.3	10	<p>It might be the case that some of the assumptions are related to flight crew training which should be traced to the Operational Evaluation Board process (as applicable) for compliance with OSD Flight Crew Data. We also believe this would reinforce the much needed integration between safety assessment process and operational evaluation (flight crew training), including for authorities that have not implemented the OSD model.</p>	Consider adding the traceability of validated assumptions to the flight crew training program to highlight the importance of traceability from system safety assessment to operational evaluation.	Recommended	Not accepted.	See comment #186

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
208	EMBRAER S.A.	3.3	10	Validation and verification, according to SAE ARP 4754A, are two different activities that occur during the aircraft/system development process. In the system level, verification activities may be recorded in the SSA (System Safety Assessment). Therefore it is suggested that any verification activity record may be jointly submitted with the Safety Assessment or within it.	<p>To replace the phrase:</p> <p>The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.</p> <p>With this new one:</p> <p>The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide a statement that all assumptions have been validated and/or verified prior or jointly with the submission of the final safety assessments.</p>	Requested	Accepted	Text reworded

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
209	TCCA - NAC	3.3 Traceability	10	<p>In Section 3.3, it is stated that the expected flight crew behaviour must be documented as an assumption as part of the safety assessment process and a process must be defined to validate these assumptions.</p> <p>However, what kind of eligibility criteria is fitting for such personnel (pilots, engineers, HF, etc.) would qualify for such a validation and verification?</p> <p>Note: Some OEM manufacturers may have used pilot evaluation matrix (PEM) to achieve extensive HF coverage of a changed system.</p>	<p>Suggested wording for Section 3.3:</p> <p>The expected flight crew behaviour must be documented as an assumption as part of the safety assessment process. A process must be defined to validate these assumptions.</p> <p>The personnel who are eligible to make validation assumptions should be noted. The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.</p>	Recommended	Not accepted	Personnel involved in the validation assumptions is defined within the applicant’s process.
210	TCCA - NAC	3.3	p.10/11	For clarity and to more explicitly address the contents of this section, it is recommend changing the title of section 3.3 to “Traceability <u>to the Safety Assessment Process</u> ”.	As noted in comment.	Requested	Noted	Title is deemed to be clear

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
211	TCCA - NAC	3.3	p.10/11	<p>“A process must be defined <u>and documented per section 3.2</u> to validate these assumptions, <u>and ensure traceability to the supporting V&V evidence</u>. The applicants <u>must also define and document</u> should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide...”</p> <p>The ‘process to validate assumptions’ is the subject of this whole proposed CM, and definition of this process is covered under section 3.2. This should be clarified. It is also recommended to strengthen wording from "describe process" to “define and document” process.</p>	Recommend updating wording as noted in comment.	Requested	Accepted	Text reworded accordingly
212	Collins Avionics	3.3	10	Last sentence states, “...and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.” If operational procedures and training material has to be released so that the validation of the assumptions remains true, then there may be a process sequence issue, especially since safety analysis are necessary in support of Type Inspection Authorization (TIA) or equivalent to start the certification flight testing.	Provide clarification how assumptions dependent on documentation post type inspection are to be handled.	Requested	Not accepted	This case is not applicable for flight test within European Union.
213	General Aviation Manufacturers Association (GAMA)	3.3	10	For smaller change projects, does the process need to document at the airplane level (assuming this means an SPP type document)?	EASA to clarify on the types of documentation that can be used to contain the process description.	Requested	Noted	This is clarified in section 4

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
214	Boeing	3.3 & 4	10	On Page 10, the CM states “The applicant should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions and provide a statement that all assumptions have been validated and/or verified prior to submit to the final safety assessments.” It is unclear if scope “all assumptions” is the same for TCs, STCs, and ATC programs.	Boeing requests EASA to clarify if “all assumptions” in Section 3.3 only applies to the applicable items identified in Section 4. Based on what is identified in Section 4, Boeing would recommend rephrasing the statement as follows: The applicant should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions and provide a statement that all applicable assumptions, within the scope of the applicant’s project, have been validated and/or verified prior to submitting to the final safety assessments.	Requested	Accepted	Text reworded in section 3.3 (“all relevant assumptions”) to clarifies that the CM applies to the applicable items in section 4.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
215	UK CAA	3.3 Traceability	10	A key element of the validity of FHA assumptions requiring a specific pilot response is the associated flight crew training, OSD-FCD (Panel 2). This is not covered in the CM.	<p>The CAA believes that to “close the loop” and ensure sufficient traceability, the applicant should be required to demonstrate that major and hazardous conditions requiring specific pilot action are covered specifically and adequately in the OSD-FCD, and that the authority is given the opportunity to validate this, for example through review of the FCD followed by a simulator session.</p> <p>Furthermore, where non-normal conditions requiring specific pilot action can be demonstrated and assessed safely in flight, the authority should be provided the opportunity to assess the most serious and complex of these cases during verification and validation flights.</p>	Recommended	Noted.	The comment is valid however the CM focus specifically on CS25.1309. (see comment #186)

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
216	Gulfstream Aerospace Corporation	3.3, Sentence 3	10	<p>“The applicants should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions (to an AFM procedure for instance) and provide a statement that all assumptions have been validated and/or verified prior to submit the final safety assessments.”</p> <p>Assumption can be a source for creating requirements. These requirements are used to define the aircraft/system architecture. The verification activity is needed to demonstrate the architecture meets the requirements. Therefore, there is no verification activity directly associated to assumptions.</p>	Reword this sentence to read “[...] provide a statement that all assumptions have been validated and their associated requirements verified prior to [...]”.	Requested	Accepted	Text has been reworded in accordance with draft ARP4754B
217	FAA AIR-710	4	10	The first sentence refers to CS25.1302, though this CM title only references CS25.1309. What is the intent of this CM?		Requested	Noted	Reference to CS25.1302 has been removed in order to clarify applicability.
218	FAA AIR-710	4	10	<p>The first paragraph states, “major changes (or STCs) to a type design...”</p> <p>STC applicants may not have access to historical data on the aircraft under evaluation. Only the manufacturer holds historical data on the non-derivative product. This data is proprietary data to the manufacturer. How does EASA intend to force manufacturer to provide proprietary data to outside aircraft modification companies?</p>		Requested	Accepted	The applicability is decided on a case by case basis and the reference to STC has been removed. It is not EASA intent to request access to historical data for STC applicant in frame of this CM.
219	AIRBUS DS	4	10	Applicable certification basis is defined as per Part 21.A.101. Airbus DS suggests to delete “or any major change “ for the applicability of this certification memo in the sentence. “or any major change that introduces new failure conditions or significantly affects existing failure conditions (change in cockpit effects or in assumed pilot reaction) on Large Aeroplanes.”	Airbus DS suggests to delete “or any major change “ in the sentence.	Requested	Not Accepted	It is correct that the applicable certification basis is defined as per Part 21.A.101. Nevertheless, the application of this CM will be discussed on project level on a case-by-case basis. The CM will not be applied on individual projects as part of the certification basis.

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220	AIRBUS DS	4	10	<p>It is not clear if the condition “that introduces new failure conditions or significantly affects existing failure conditions (change in cockpit effects or in assumed pilot reaction) on Large Aeroplanes.” is applicable to significant major change (or STCs) to a type design.</p> <p>Airbus DS considers that the Certif memo is relevant only in case of introduction of new failure conditions or significantly affecting existing failure conditions, when related to the change in cockpit effects or in assumed pilot reaction on Large Aeroplanes</p>	<p>Airbus DS suggests to reword as follows:</p> <p>“The guidance in this Certification Memorandum affects applicants showing compliance with CS 25.1309 and CS 25.1302 for certification of a new type design, significant major changes (or STCs) to a type design or any major change, <u>in case it</u> introduces new failure conditions or significantly affects existing failure conditions, <u>related</u> to the change in cockpit effects or in assumed pilot reaction on Large Aeroplanes. The application will be discussed on project level on a case-by-case basis.”</p>	Requested	Not accepted.	In case of a change to an approved design, the CPR process will be followed. The CM does not take precedence over the CPR.

221	Independent Aircraft Modifier Alliance (IAMA)	4	10	<p>The current definition of the applicability of this CM, “discussed on project level on a case-by-case basis” is too vague leading to risk to certification programs and possibly result in unnecessary compliance demonstration or subjective dismissal of this CM</p>	<p>Definition of the Failure Classifications at which this CM becomes applicable; i.e. Failure Conditions where Flight Crew action is utilized as Justification and/or Mitigation with a Failure Classification of Hazardous or Catastrophic.</p> <p>Alternatively, those Failure Classifications of NSE / MIN / MAJ could be deemed such that this CM does not apply.</p> <p>In addition, we suggest to link the existing risk-based Compliance Demonstration Items (per LOI) into the applicability. For this, we suggest that for a CDI defined as Non-Complex and Non-Critical, this CM shall not apply.</p> <p>Finally, the definition of CS 25.1309 and CS25.1302 may be misleading if the applicant CP only includes CS25.1309. Our suggestion is to remove the references to these requirements and instead link the applicability based on the failure conditions and supporting basis as outlined above.</p>	Requested	Partially accepted	<p>1) The severity of the failure conditions for which this memo applies are given in comment #86.</p> <p>2) Application of this memo will be discussed on project level on a case-by-case basis (as per section 4)</p>
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222	Independent Aircraft Modifier Alliance (IAMA)	4	10	The applicability covers where an applicant significantly affects existing Failure Conditions. However, there is concern regarding Type Certificate Changes where the existing Human Factors Considerations for Flight Crew actions may not have been fully assessed to the same level as required by this CM.	Addition of the limit of responsibility and use of existing data as part of a Type Certificate Change such to ensure the applicant is only responsible for the Human Factors considerations between the pre and post mod Type Design	Requested	Noted	The principles of the CPR apply and define the scope of the investigation. The applicant is responsible for the Human Factors considerations between the pre and post mod Type Design change.
223	Bombardier	4	10	Although application of the methodology presented in this CM for confirmation of pilot action assumptions can be warranted for some aircraft changes, for aircraft where 25.1302 is not part of the original type design, this CM should not force the adoption of 25.1302 automatically for all changes affecting the cockpit or pilot task, introduces new failure conditions or significantly affects existing failure conditions.	Add text of the comment summary to the end of the section	Requested	Accepted	Reference to CS25.1302 is removed from the paragraph as it is not related and may bring confusion. (see comment #217).

224	Fokker Services	4 : Who this Certification Memorandum affects	10	<p>The applicability is in our opinion too wide. Especially the wording ‘The application will be discussed on project level on a case-by-case basis’ will lead to an unacceptable level of certification risk and hence business risk upfront, and may possibly result in a significant, and unnecessary, increase of compliance substantiation where this may be not justified because of the SSA hazard classification and the LOI risk level classification.</p>	<p>This can be resolved by rewording of this section as follows:</p> <p>“The guidance in this Certification Memorandum affects applicants showing compliance for certification of a new type design, significant major changes (or STCs) to a type design or any major change that introduces new failure conditions or significantly affects existing failure conditions with associated change in cockpit effects or in assumed pilot reaction on Large Aeroplanes, where the new or affected failure condition (without any credit from flight crew recognition and/or action) is classified hazardous or catastrophic AND for the risk determination for LOI of the associated CDI(s) the criteria complex and/or critical apply .”</p> <p>[The CS 25.1309 and CS 25.1302 references can better be left out as these depend on the certification basis of the aircraft, and on whether these requirements were identified in the</p>	Requested	Not accepted	<p>EASA opinion is that the expectation is proportional to the importance and the effects of the human factors assumptions in the safety assessment. In any case, there is a possibility for the applicant to discuss this CM at project level.</p>
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					certification program. Basic criterion should just be the affected failure condition with flight deck effects and hence assumed pilot reaction.] [25.1309 failure classification and LOI risk classification criteria added to bind the applicability of the approach described in the CM more objectively to those certification activities where this approach is really justified.]			
225	General Aviation Manufacturers Association (GAMA)	CM 1.1	3	<p>The proposed text reflects in 1.1 that the CM applies also to AFHA.</p> <p>There is still insufficient guidance to apply this validation technique to aircraft level functional hazard assessments. Aircraft level functional hazard assessments are more general than system level, and inherently cannot have discrete actionable failure conditions due to the integrated aircraft functional level of the conditions.</p> <p>These more general failure conditions cannot be related to discrete crew actions and tasks that can be validated or tested unless the failure conditions are further decomposed into sets of system level failure conditions.</p>	EASA to remove AFHA from CM applicability or revise CM to provide guidance on suggested methodology for airplane level crew action assumption validation.	Requested	Not Accepted	The CM applies to the AFHA as well. The aircraft level functional hazard assessment might contain assumptions of the expected flight crew behaviour.
226	General Aviation Manufacturers Association (GAMA)	CM 1.4	4	The definition of ‘validate’ is missing context with how correctness or completeness is evaluated.	EASA to clarify or expand the definition of ‘validate’	Requested	Accepted	Text reworded accordingly

227	General Aviation Manufacturers Association (GAMA)	CM 3.2 (all)	8-10	<p>The proposed CM 3.2 appears to lack clear guidance and exemplification of possible correctness or completion scenarios when validating and verifying flight crew behaviour assumptions.</p> <p>In consequence, GAMA believes language as proposed does not allow the applicant to find certainty in the process outcome and leaves room for interpretation disparity.</p>	<p>EASA to provide more certainty on how the applicant can successfully comply with the proposed CM 3.2, especially by providing examples/clarification/measurable criteria in reference to:</p> <ul style="list-style-type: none">– The consideration of ‘expert judgement’;– The concept of ‘degree of confidence’, including clarification on whether the level of scrutiny analysis has to take into account only assumptions from the FHA or all post failure behaviour;– Aligning ‘very high degree of confidence’ method with the expected deliverable, as ‘expert judgment only’ does not imply evidence.– Better describing the difference between very high degree of	Requested	Not accepted.	<p>It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason EASA will not comply with the request to define more specific criteria.</p>
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					<p>confidence and high degree of confidence</p> <ul style="list-style-type: none"> – The meaning and extent of ‘additional data’, specially if or how the data is tied to the task analysis model table. <p>The determination of successful/unsuccessful flight crew behaviour assumptions verification and validation when using a scenario-based approach (i.e. how many crews have to perform as assumed?)</p>			
228	General Aviation Manufacturers Association (GAMA)	CM 3.2, 4 th paragraph	8	<p>EASA states, on page 8: “This approach should be considered during all systems certification plans and the System Safety Assessments (SSA) reviews utilising multi-disciplinary teams (e.g. Engineering, Flight Test and HF).”</p> <p>It seems that language as proposed does not provide clarity on the scope of the statement.</p>	EASA to rephrase the statement limiting the scope of the process only to SSA’s human factors aspects.	Requested	Noted	First paragraph in section 3.2 clarify the scope of the statement (and of the full paragraph).
229	General Aviation Manufacturers Association (GAMA)	CM 3.3, CM 4	10	<p>On Page 10, EASA states “The applicant should describe in an aircraft-level document, the process that will be used to ensure the traceability of assumptions and provide a statement that all assumptions have been validated and/or verified prior to submit to the final safety assessments.”</p> <p>From this statement, it is unclear if the scope “all assumptions” is the same for TCs, STCs, and ATC programs.</p>	EASA to clarify if “all assumptions” in Section 3.3 only applies to the applicable items identified in Section 4.	Requested	Noted	See comment #214

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
230	Volocopter GmbH	Fig 1	9	The second and third questions of the flowchart exit gate (square-shaped) of figure 01 are understood to be answered by safety engineer based on engineering judgment. A guidance on how to assess the confidence on crew behaviour is needed and the CM should either provide one or indicate Applicants to establish one to be accepted by Authority before use.	Provide confidence degree guidance or state the Applicant shall define one and agree its usage with Authority.	Recommended	Not accepted.	As described in the paragraph 3.2 the categorisation process should be adequately documented and presented, the outputs of this process should be provided to the authority. The process presented in figure 01 (flowchart) provides an acceptable approach. The following activities are meant to be run by a multi-disciplinary team consisting of relevant discipline representatives (e.g. Engineering, Safety, Flight Test and HF). Therefore, EASA considers that the concern expressed by Volocopter is adequately addressed in the proposed CM.
231	BAE SYSTEMS	Fig 1	9	Not clear what ‘full human factors process’ is.		Requested	Noted	Full HF process implies the potential combination of MoC and is likely to include scenario-based approach as per presented in the table 2.
232	BAE SYSTEMS	Fig 1	9	‘degree of confidence’ is highly subjective. What would be accepted by the authority as evidence to support this degree of confidence?		Requested	Noted.	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason, EASA will not comply with the request to define more specific criteria.
233	Volocopter GmbH	Fig 1 Table 2	9	The flowchart exit gate (square-shaped) of figure 01 are understood to be the ‘confidence degree’ of table 2. Nevertheless, there is no clear traceability between the two i.e., the wording of the flow chart is different form the one used in ‘confidence degree’ column of table 2.	Write the confidence degree level of table 2 as title for the exit gate of flow chart 1.	Recommended	Partially accepted.	Schematic modified to be consistent with following table.
234	Honeywell	Figure 01	9	First decision point: “Does the failure consequence take credit from flight crew recognition and/or”	Should be “take credit for” not from	Recommended	Accepted.	Text modified as proposed. To be checked by proofreading.
235	EMBRAER S.A.	Figure 01	9	The terminology “level of scrutiny” is also used in AMC 25.1302, where it has a descriptive criteria not necessarily applicable to the present memorandum.	Replace “level of scrutiny” by “level of rigour”.	Recommended	Not accepted	The level of scrutiny is not a terminology that is specific to 25.1302. The criteria proposed by the applicant to determine the depth of the means selected to validate the assumptions about flight crew behaviours may be different from the ones provided in the context of 25.1302 demonstration.

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236	EMBRAER S.A.	Figure 01	9	It is not clear in the document the definition of “very high degree of confidence” and “high degree of confidence”.	Include definition of “very high degree of confidence” and “high degree of confidence” in section 1.4.	Requested	Not accepted.	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason, EASA will not comply with the request to define more specific criteria/definition.
237	Collins Avionics	Figure 01	9	There should be a clear starting point to the flow diagram. Is this flowchart applied to the outputs of the Task Analysis Model?	Flowchart should define the starting point and inputs into the process flow	Requested	Not accepted	As mentioned in paragraph 3.2, the flow chart applies to “ each applicable system failure condition ”.
238	Collins Avionics	Figure 01	9	There is no guidance for the difference between “very high degree of confidence” and “high degree of confidence”; these terms can be ambiguous.	Provide additional guidance on how to determine the difference between “very high degree of confidence” and “high degree of confidence”.	Recommended	Not accepted.	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason, EASA will not comply with the request to define more specific criteria/guidance.
239	Gulfstream Aerospace Corporation	Figure 01. Diagram – level of scrutiny	9	This diagram’s underlying assumption is that crew behaviour is predictable which it is not, and that the aircraft manufacturer can predict that behaviour with certainty.	Use the existing 25.1302 guidance for level of scrutiny and delete the diagram.	Requested	Not accepted	EASA does not agree with Gulfstream’s interpretation of the diagram. It is the intent of the process to verify the assumptions, hence it assumes that crew behaviour assumptions are not certain. EASA considers the diagram as useful and propose to keep it in the CM.
240	Honeywell	Figure 1 Table 2	9 10	For the process steps defined in Figure 1 & Table 2, the difference between a “very high” and “high” degree of confidence in predicting crew behaviour is not clearly illustrated and will be subjective.	Provide additional guidance on how an applicant can make this definition to avoid misinterpretation. For example, this may consider complexity of the failure scenario, information presented to the flight crew, and actions taken by the flight crew.	Recommended	Not accepted.	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason EASA will not comply with the request to define more specific criteria/guidance.

NR	Name of the organisation commenting	Section, table, figure	Page	Comment summary	Suggested resolution	From the commenter point of view a modification of the published text is*:	EASA comment disposition	EASA response
241	HeliOffshore	Figure 1	9	<p>In the Flowchart, the level of scrutiny is determined by confidence in crew behaviour, without stating how this should be determined. We would suggest firstly that assumptions in this regard are comprehensively detailed and secondly that scenario-based simulator trials where the crew are faced with a challenging situation that includes distractions and high workload. Crucially, the pilot should not be briefed on the situation to be tested nor on the behaviour expected of them. Arrangements should also take into account that given the opportunity, test subjects will talk to each other when they leave the simulator. In addition, difficult but not extreme workload scenarios, with reasonable levels of distraction should be used when considering the potential for human error.</p> <p>The assessment of whether the crew can respond or not needs to take into account workload from other tasks and sources of distraction. These have been shown to be two of the things that slowdown both detection and response. Also, the criticality of the human or equipment failure modes may depend on phase of flight and this should be taken into account.</p>	Amend the flow chart and add section on how to make determination of whether analysis is required.	Requested	Not accepted.	<p>EASA concur with HeliOffshore on the HF best practices mentioned. EASA kindly remind that these best practices are already detailed in the current AMC25.1302 and even further developed in the upcoming AMC25.1302 update. This material is quoted in the CM (paragraph 3.2), therefore EASA considers that sufficient guidance is provided to applicants to ensure EASA expectations are fulfilled.</p> <p>Finally, considering the workload aspects, EASA takes notes of HeliOffshore’s position, however for EASA the focus of HF investigations should not be limited to workload.</p>

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242	HeliOffshore	Figure 1	9	<p>In the Flowchart, the level of scrutiny is determined by confidence in crew behaviour, without stating how this should be determined. We would suggest firstly that assumptions in this regard are comprehensively detailed and secondly that scenario based simulator trials where the crew are faced with a challenging situation that includes distractions and high workload. Crucially, the pilot should not be briefed on the situation to be tested nor on the behaviour expected of them. Arrangements should also take into account that given the opportunity, test subjects will talk to each other when they leave the simulator. In addition, difficult but not extreme workload scenarios, with reasonable levels of distraction should be used when considering the potential for human error.</p> <p>The assessment of whether the crew can respond or not needs to take into account workload from other tasks and sources of distraction. These have been shown to be two of the things that slowdown both detection and response. Also, the criticality of the human or equipment failure modes may depend on phase of flight and this should be taken into account.</p>	Amend the flow chart and add section on how to make determination of whether analysis is required.	Requested	Not accepted.	See EASA position on comment #241.
243	ADSE B.V. The Netherlands	General	N/A	<p>We applaud the effort to build the bridge between 25.1302 and 25.1309. Making the interplay between the Human Error point of view, the Human Performance point of view and the System Safety point of view more robust is a step that we support.</p>		Not requested	Noted	EASA concur and thanks ADSE B.V The Netherlands for this very supportive feedback.

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244	Heart Aerospace AB	general	3 and 4	<p>On page 3, the Proposed CM-SA-002 states that “Recent experience has shown that a disparity may exist between: - the observed flight crew behaviours, and - the underlying assumptions about flight crew recognition, interpretation, and response that applicants have made during the design and certification process”.</p> <p>A given failure could contribute to more than one failure condition.</p> <p>Disparity may exist when a given failure is recognized and perceived (or not) by flight crew, but the assumptions about flight crew recognition, interpretation, and response are made in FHA for a (one) given failure condition.</p>	Heart Aerospace AB suggests replacing “ failure condition recognition ” to “ failure recognition ” on Page 4.	Recommended	Not Accepted	Text is line with the AMC 25.1329.
245	AIRBUS DS	general	1	Airbus DS fully agree with the overall intent of this certification Memo and its objective to support proper Failure Case classification and traceability improvement on Large Aeroplane under CS-25 regulation.	N/A	Not requested	Noted	Noted.

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246	ANAC	General	N/A	<p>The CM does not limit the failure conditions (in terms of their severity) which are subject to this guidance. Instead, section 3 states all of them are, as long as they take credit of flight crew actions to determine the severity classification. However, it seems to make more sense to focus on the failure conditions that would be CAT or HAZ if the flight crew actions are not accomplished as expected. Alternatively, if the CM aims at addressing all failure conditions that take credit of flight crew actions, the level of scrutiny (Figure 01) should depend not only on the degree of confidence in the flight crew behaviour assumption, but also on the failure condition severity if the flight crew actions are not accomplished as expected. (Note: the CM mentions “applicable system failure conditions” without further explanation.) It is worth considering that, taking into account the guidance provided in ARP4754A/ED-79A section 5.4.2.d, besides thoroughly recording and assessing all assumptions, the main concern then is on assumptions that, if erroneous, could have significant potential to reduce safety.</p>	<p>Focus applicability of the CM on the failure conditions that would be CAT or HAZ if the flight crew actions are not accomplished as expected.</p> <p>OR</p> <p>Change level of scrutiny (Figure 01) so that it does not depend only on the degree of confidence in the flight crew behaviour assumption, but also on the failure condition severity if the flight crew actions are not accomplished as expected.</p>	Requested	Not accepted	See comment #86

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247	ANAC	General	N/A	In many instances, the CM refers to the need of verifying assumptions made about flight crew. We understand that the use of the term verification is not appropriate when related to assumptions. Assumptions are “statements, principles, and/or premises offered without proof”, i.e. by their definition, assumptions are not “verifiable”. This is reflected in ARP4754A/ED-79A 5.4.2.d “Management and Validation of Assumptions” that does not mention verification of assumptions. Essentially, this guidance (also recognized as means of compliance with CS 25.1309) directs the applicant to manage and validate the assumptions in a process focused on judging their reasonableness and managing potential impacts if they are not confirmed.	<p>Suggest removing all occurrences of the term verification when related to assumptions, since verification is only possible for requirements, not assumptions. In alignment with ARP4754A/ED-79A, ANAC recommends that instead of using “validation and verification of assumptions”, EASA reinforces the need that assumptions must be “managed and validated”.</p> <p>OR</p> <p>Given the introductory paragraph of section 3.2 mentions verification of assumptions “(as required)”, we recommend that additional guidance is provided on the specificities of verification activities in the context of assumptions in this CM, and when these verification activities are required.</p>	Requested	Accepted	Text reworded accordingly

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248	UK CAA	General	General	Please can EASA confirm that this CM is not intended to alter the base safety assumption that the probability of human error is 1?	None – this is a question.	Not requested	Noted.	EASA confirms that the intend of this CM is not to alter the assumptions of human error.
249	EMBRAER S.A.	General	1-11	<p>This Certification Memo goes beyond what is expected from a Certification Memo as it contains a methodology for compliance demonstration to §25.1309, regulated by its specific AMC.</p> <p>This Certification Memo also relates to the principles of compliance demonstration to §25.1302, regulated by its specific AMC.</p> <p>It is understood that EASA recognizes the link between §25.1309 and §25.1302. However, it is believed that EASA should consequently address this link by regular rulemaking activity.</p> <p>Moreover, EMBRAER would like to point out that bypassing normal rulemaking process through the inadequate use of Certification Memo’s, may, eventually, jeopardize requirement harmonization between Authorities, EASA and FAA.</p>	EASA should address the introduction of a methodology for compliance demonstration to §25.1309 by regular rulemaking activity.	Requested	Not Accepted	<p>It is reminded that:</p> <p>Quote <i>EASA Certification Memoranda ... are intended to provide guidance on a particular subject and, as non-binding material, may provide complementary information and guidance for compliance demonstration with current standards. Certification Memoranda are provided for information purposes only and must not be misconstrued as formally adopted Acceptable Means of Compliance (AMC) or as Guidance Material (GM).</i> Unquote (see text in the preamble on page 1 of the CM)</p> <p>In addition, a harmonisation activity with FAA, TCCA and ANAC has been initiated in order to further strengthen harmonisation of interpretation between authorities.</p> <p>At a later stage, when sufficient experience has been gathered with the application of the CM to individual projects and if the content of the CM is considered sufficiently mature, it might be introduced to the Certification Specifications (AMC part) in the context of a NPA, applying the usual rulemaking process.</p> <p>This is considered as normal process at EASA.</p>
250	HeliOffshore	General		Congratulations on this positive step towards integration of Human Factors into System Safety Assessment, we are very supportive of this direction.		Not requested	Noted	

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251	TCCA - NAC	General	Multiple	In multiple places through this document the terminology “flight crew behaviour” is used. In the current regulations and guidance, the term "behaviour" is used in relation to systems. In relation to crew - "flight crew actions", "flight crew performance" are typically used.	Consider using the more common terminology such as flight crew actions.	Recommended	Not accepted.	From EASA perspective, Flight crew behaviour is broader than flight crew actions or performance and therefore more suitable. Finally, it is also aligned with the proposed amended CS25.1302 wording.
252	Fokker Services	Generic question / comment		How will the approach described in this Certification Memorandum be harmonized with the US FAA?		Recommended	Noted.	A draft version of this Certification Memo was shared with the FAA. The FAA comments were integrated before the publication consultation. After the publication of the proposed CM, an authority working group with the FAA, TCCA, ANAC and EASA was initiated on EASA’s request. This group aims to provide a forum for authority to exchange and harmonise on the wider subject of the consideration of Human Factor in Safety Assessment.
253	Fokker Services	Generic question / comment	10	How will it be excluded that the application of the change may lead to a level of compliance activity (for a change) far exceeding the work for the basic design based on the applicable certification basis?	Replace “The application will be discussed on project level on a case-by-case basis.” by “The application is not intended to require a more detailed and deeper assessment for a change than as applied for the existing design, or to require a re-evaluation of the broader existing design to which the change is applied. The certification basis of the aircraft shall be duly considered and acknowledged in this respect.”	Requested	Not Accepted	The clarification that the application will be discussed on project level on a case-by-case basis is retained. There is no direct relation seen between the level of compliance activity required for the actual change and the existing design. In case that a more complex design is introduced by the actual change compared to the previously approved original design, this may require a more detailed and deeper technical investigation of flight deck effects and associated (assumed) flight crew responses. (Please also refer to EASA response for comment #219)

254	HeliOffshore	New Section		<p>Common Accident Scenarios - In order to maximise safety, the most common accident scenarios could be considered for the opportunities to better support the pilot or mitigate the possibility of an accident. For example:</p> <ol style="list-style-type: none"> 1. If Controlled Flight into Terrain (CFIT) is the common accident scenario, a Terrain Awareness Warning System (TAWS) could be fitted as mitigation. This is not because the absence of TAWS makes the aircraft unsafe, but because the addition of the TAWS system could be the best opportunity to improve safety. 2. If a particular task is identified as having high consequence in the event of pilot error, the procedure could be adjusted to reduce distraction or workload at that time (e.g. sterile cockpit procedure). 3. If a certain human error may develop into an unsafe situation, an indication or alert could be added, and the cockpit features, procedures and documentation could be made as user friendly as possible. This already occurs in reaction to situations that have already ended in an accident (e.g. a detailed AMC is provided for maintenance and checks of Thrust Reversers in AMC 25.933 probably in response to the Lauda Air disaster of May 1991) but is not implemented in a systematic or proactive manner – i.e. such changes should be applied to all such situations not just on thrust reversers. The type of mitigation should be commensurate with the severity of the potential consequence of error. For example the most severe consequences should be prevented by design, serious should be made less likely by design and / or accompanied by an alert, moderate should be addressed by design where feasible or by procedures, minor may be addressed by training but only for the error types where training is an appropriate mitigation, remembering that: <ol style="list-style-type: none"> a. slips and lapse type error are not reduced by training b. mistakes due to limited understanding are well addressed by training c. manual skills and response speed are helped by recurrent training / practice 	Add a section suggesting that common accident scenarios should be considered as part of the analysis.	Requested	Not accepted.	EASA agrees that interest can be found in considering accident scenarios while conducting FC analysis, however, the approach should be proposed to the EASA and discussed at project level not in the CM content.
255	HeliOffshore	New section		Foreseeable error types - In addition, a list of ‘foreseeable error types’ should be developed that should always be considered, in addition to any errors identified during	Add a section requiring that foreseeable error	Requested	Not accepted.	EASA agrees that interest can be found in considering common errors while conducting FC

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				<p>simulator trials or proposed by Test Pilots. This would counterbalance the rarity of errors that might not be observed in the simulator and any temptation to exclude known common error types from the analysis. It could include:</p> <ul style="list-style-type: none"> • Action not performed, or performed too late (e.g. no intervention) • Action on wrong control (e.g. shut down wrong engine) • Action performed incorrectly (e.g. wrong setting, wrong control input) • Indications not seen or misread (e.g. pilots both distracted by other factor) • Indications interpreted incorrectly (e.g. misdiagnosis of situation possibly due to symptoms consistent with different problem) 	types are considered as part of the analysis.			analysis, however, the approach should be proposed to the EASA and discussed at project level not in the CM content.
256	GE Aviation – Human Factors	Paragraph 1 – first sentence, below Table 2	10	Consider how scenarios may differ between a simulator and the actual airplane when selecting the scenario environment. Sounds, noise, vibration, etc. that cannot be mimicked in a simulator could result in a different response by the flight crew real world.	Add additional language about scenarios that are recommended in the aircraft due to the unique environmental conditions that cannot be replicated in a simulator.	Recommended	Not accepted.	Best practices related to MoC use depending on test perimeter are already detailed in the current AMC25.1302 and even further developed in the upcoming AMC25.1302 update. This material is quoted in the CM (paragraph 3.2), therefore EASA considers that sufficient guidance is provided to applicants to ensure EASA expectations are fulfilled.
257	Honeywell	Table 02	10	<p>Deliverables- row3 “Test plans and Reports.”</p> <p>This list of deliverables seems limited compared to the corresponding means column.</p>	Add “Analyses or Review Reports” which follows the progression in the table. A sentence explaining that progression would be helpful.	Requested	Accepted.	Text amended accordingly.

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258	Boeing	Table 1	7	On Page 7 in Table 1, the CM references basic airmanship in the Flight Crew Response field for Failure Case #1.	Boeing requests that EASA add the definition for “basic airmanship” to Section 1.4: Definitions.	Requested	Not accepted.	There is not “Basic airmanship” agreed definition available.
259	Honeywell	Table 1	7	#4 “What part of the training syllabus is assumed to be used in the context of the failure management?” - For new and novel functions or early in development process, this may not be applicable and should be developed Application during development will be limited	Change wording to “What part of the training syllabus needs to be developed in the context of the failure management?”	Requested	Not accepted.	As mentioned in paragraph 3.2, “It is recognized that the safety assessment is an iterative process. It is assumed that training syllabus might not be available or mature when the verification process is started, however the assumptions will need to be reconsidered based on the evolving maturity of the training syllabus.
260	Honeywell	Table 1	7	#4: Does not capture or account for automation aids or assistants that may be assumed for resolution.	Suggest adding “What automation assistant/tools are assumed to be used if any”	Requested	Not accepted.	EASA considers that the current questions presented in the table are already tackling appropriately the crew response. The topic of automation is not seen sizing for EASA in such case.
261	Honeywell	Table 1	7	Failure case #1, item 4 Flight crew response includes the question “Which procedure(s) is (are) assumed to be used?.” It seems that failure case #2 could also ask the same question, if applicable certain failure cases which are observable can also have an associated flight crew procedure. For instance, an observable erroneous primary flight indication or a complete loss of a single primary flight indication may include a procedure to check that indication vs the opposite side or a standby indication, and perform a reversion.	Include the question in Failure case #2, item 4 Flight crew response “Which procedure(s) is (are) assumed to be used?”	Recommended	Accepted.	Text added from previous comment.

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262	ADSE B.V. The Netherlands	Table 1	7	<p>The naming “Failure case#1” and “Failure case#2” provides misinterpretation of the meaning.</p> <p>First of all, in the text in paragraph 3.1 the naming is “Failure Management Case #1” and “Failure Management Case #1”, and thus differs from the naming in the table.</p> <p>Secondly, the use of the wording “Failure case” can be confused with failure cases that need to be analysed in the 1309 analysis itself.</p> <p>Proposed text change: Use the wording “type” or “situation” i.s.o. the word “case” in this context.</p>		Requested	Not accepted.	EASA is not sure on comment intent. “Failure case” wording is considered appropriate as it is EASA intent to deal with failure cases to be analysed in the context of CS25.1309.
263	Boeing	Table 1	7	<p>The task framework outlines that the failure case #1 and #2 would be determined prior to completing the analysis.</p> <p>Boeing believes the analysis would determine this categorization.</p>	No suggested resolution.	Not requested	Noted.	
264	Boeing	Table 1	7	<p>On Page 7 in Table 1, the CM mentioned unusual workload in the Post Failure Management field.</p>	Boeing requests that EASA add the definition for “unusual workload” to Section 1.4: Definitions.	Requested	Not accepted	<p>EASA intent is for the applicant to report levels (concentration, force or workload) that are not usual in the operation of the aircraft. These levels will be later assessed for their acceptability (excessive, unacceptable...), nevertheless EASA is targeting a delta in workload, concentration, force compared to before failure situation.</p> <p>EASA does not see the need to precisely define nor provide specific metrics for: “unusual workload”, “unusual concentration”</p>
265	Boeing	Table 1	5	<p>On Page 7 in Table 1, the CM mentioned unusual concentration in the Post Failure Management field.</p>	Boeing requests that EASA add the definition for “unusual concentration” to Section 1.4: Definitions.	Requested	Not accepted.	<p>EASA intent is for the applicant to report levels (concentration, force or workload) that are not usual in the operation of the aircraft. These levels will be later assessed for their acceptability (excessive, unacceptable...), nevertheless EASA is targeting a delta in workload, concentration, force compared to before failure situation.</p> <p>EASA does not see the need to precisely define nor provide specific metrics for: “unusual workload”, “unusual concentration”</p>

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266	Boeing	Table 1	7	On Page 7, the CM states “What are the actions the flight crew is obliged to accomplish manually due to the failure?” The intent and scope of question seem unclear.	Boeing requests that EASA provide additional information to help the applicant understand the intent of this question.	Requested	Accepted.	Text has been modified to clarify intent: “What are the actions the flight crew is obliged to accomplish manually due to the resulting failure effect for the rest of the flight?”
267	Boeing	Table 1	7	Failure Case #1, as interpreted, is meant for failure conditions which are indicated to the crew (be it primary or secondary failures which are being alerted) as long as all alerts are unambiguously presented to the crew.	Failure case#1: Boeing recommends that EASA revise “Explicit alert from the Crew Alerting System (CAS) unambiguously pointing to the primary failure” to “Explicit alert(s) from the Crew Alerting System (CAS) that unambiguously directs the flight crew to a specific procedure”	Requested	Not accepted.	Text has been already modified as follow to address previous comment: “Explicit alert from the Crew Alerting System (CAS) unambiguously pointing to the initial failure”
268	Volocopter GmbH	Table 1	8	The term “alert pointing to the primary failure” is understood to correspond to an “umbrella alert” in AMC25.1322 meaning. From this definition, It is not clear if a “collector alert” that groups alerts sharing different causes could be also considered under Failure case #1, although it also aims to resolve problems of insufficient space or periodisation of multiple alerts, and points to a single procedure, on contrary to the failure cases #2.	Clarify the scope for “Failure case #1” with regards to the “explicit and unambiguous” criteria of the alert	Requested	Partially accepted.	Text has been already modified as follow to address previous comment: “Explicit alert from the Crew Alerting System (CAS) unambiguously pointing to the initial failure”. Modification should clarify the scope.
269	Volocopter GmbH	Table 1	9	“Which of the two cases characterize the FHA?” This sentence is not clear. The cases are related to the FC recognition, not to the “FHA”.	Propose to replace by “Which of the two cases characterize the Failure Condition or the FC scenario(s)?”	Requested	Accepted	Text reworded

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270	Volocopter GmbH	Table 1	10	<p>“Perception” and “Flight Crew Response” for the failure case #1.</p> <p>When “umbrella alerts” are used to mask all secondary effects and alerts resulting from the common cause, it is expected to validate also the final level of alert (considering the need for crew awareness and response for secondary effects) and the overall procedure with regards to the sequence of actions needed.</p>	Recommend to explicit validation activities needed when design choices have been made for the EICAS system to mask secondary or cascading alerts.	Recommended	Not accepted.	For EASA, the whole CM content is addressing the validation activities required for each failure condition whatever the design choice made by the applicant. Hence the concern expressed by Volocopter is, from EASA perspective, covered.
271	BAE SYSTEMS	Table 1	7	Use of the term ‘Task Analysis Model’ in this context could be confusing as it is also used as a method for decomposing human tasks		Requested	Noted.	Indeed the term can have a different meaning, however the CM content is detailing the expected activities, hence no confusion should remain.
272	Heart Aerospace AB	Table 1	6 and 7	For the description of Failure case #1: the task analysis model should not exclude the possibility for additional symptoms (especially, Flight Deck effects and/or aircraft physical feedback).	In the initial paragraphs of item 3.1, before Table 1, Heart Aerospace AB suggests to add that the Failure Cases #1 and #2 are not mutually exclusive (and that most of the cases will be a combination).	Recommended	Not accepted.	From EASA perspective, should additional “symptoms” being present and used by the crew to understand the situation, the situation would then belong to case #2.
273	Heart Aerospace AB	Table 1	7	In the 5. Post failure management, the <u>physiological aspects</u> on the crew are missing as a proposed description. It is however believed that the physiological context may be relevant in the failure management human factor aspects.	<p>Heart Aerospace AB suggests the following addition:</p> <p>“- Are there some physiological impacts that are susceptible to emerge and modify the crew performance in responding to the scenario ? (e.g. temperature runaway, excessive noise or vibration, visibility degradation in the flight deck, etc.)”</p>	Requested	Accepted.	Text added accordingly.

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274	Heart Aerospace AB	Table 1	7	<p>In Table 1, item 5. Post failure management, the <u>delayed effects</u> to be considered are missing.</p> <p>An example could be: the loss of power for the ventilation of an Avionics bay does not have immediate effects, but 10-15 min later, the temperature increase may lead to the failure of some equipment. This may happen in a rather unpredictable way (list of equipment which fail, timing and order of the failures, etc.).</p> <p>This is important to mention them since it may confuse the crew while the crew thinks that it has recovered the situation. The linkage of the new effects to the primary failure condition may not be understood.</p>	<p>Heart Aerospace AB suggests the following addition:</p> <p>“- Are there some potential consequences that may occur in a delayed way compared to the primary failure ? What are the means to allow the crew to anticipate these effects ?”</p> <p>An example such as given in this line may be useful to help the reader understand.</p>	Requested	Not accepted.	<p>EASA considers that the below quoted lines extracted from part #5 of the table 1 addresses the dimension highlighted by Heart Aerospace:</p> <p>“What are the consequences of the failure condition on the aircraft systems (inoperative systems, unavailable systems, reversibility of the status, etc.)?”</p> <p>What are the operational limitations to be respected due to the failure (e.g.: altitude, speed, temperatures...)?”</p>
275	EMBRAER S.A.	Table 1	7	On “Failure case#1”, even if this case is applicable for failure condition with specific alerts as CAS messages, the condition might also include secondary flight deck effects.	On “Failure case#1” include a note: “Note: Even if there are secondary flight deck effects.”	Recommended	Not accepted.	Item #1 of Table 1 is already addressing the concern expressed by Embraer S.A. (“Note: It can be a combination of both cases.”).
276	EMBRAER S.A.	Table 1	7	On “Failure case#2”, it is not clear what are the “Other observable Flight deck effects”.	On “Failure case#2” include examples of other observable flight deck effects.	Recommended	Not accepted.	“Other observable flight deck effects” is considered self-explanatory. In order to avoid unnecessary lengthy paragraph, information in CM is kept as concise as possible as long as clarity is ensured.
277	EMBRAER S.A.	Table 1	7	It is not clear for “1. Stimulus” the text “Note: It can be a combination of both cases.” since failure case #1 and #2 intended to be mutual exclusive in the stimulus point of view.	Remove the text “Note: It can be a combination of both cases.”.	Requested	Not accepted.	This note is considered useful from EASA perspective and is also answering to Embraer S.A comment #275.

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278	EMBRAER S.A.	Table 1	7	For “2. Perception”, providing information requested for Failure case#1 seems unnecessary, since they are covered by 25.1322 process.	Remove the information required for “2. Perception” and indicate the applicability of compliance demonstration for 25.1322.	Recommended	Not accepted.	The information to be collected as per Table 1 Item #2 is considered necessary by EASA to appropriately analyse and verify the assumption made with regards to Flight crew behaviour. Even if more guidance can be found in AMC25.1322, compliance with CS25.1322 is not considered sufficient by itself to fulfil CM proposed guidance.
279	EMBRAER S.A.	Table 1	7	In “3. Information processing”, for the question related to “time spent” in “Failure case#2”, the absolute definition of time has been shown impractical and there is currently no acceptable basis to define the time. Time is being used in a relative basis for defining prioritization among the conditions. Also, it is not practical to separate the time for flight crew perception, information processing and response. For assumptions about time, it is expected that experts judgment between manufactures and certifications authorities is commensurate with the failure classification.	Remove the question about time “What are the assumptions about the time spent from the failure detection to the flight crew response?”.	Requested	Not accepted.	EASA considers that the notion of time or delay within which the flight crew is assumed to detect the alert and/or flight deck effects is necessary to be listed as it could heavily impact the validity of the assumption made with regards to flight crew behaviour. The comments allowed EASA to identify the need to duplicate the question under the case #2 also.
280	EMBRAER S.A.	Table 1	7	In “4. Flight crew response”, for “Failure case#1” the question related to “training syllabus” assumes that all failure conditions alerted are clearly defined in a training syllabus and trained by the pilot. It is not feasible for a pilot to be trained in all failure conditions of an airplane. For example, different failure conditions might require similar pilot’s response, then not all of them necessarily need to be trained, but once pilot is trained to respond to one of them and perform read and do procedures, he/she would be prepared to address other similar failure conditions. Also, some competencies are acquired during pilot’s basic qualification and are not tied to a specific type related training. Then, it seems to be more appropriate to consider training assumptions (when applicable) than specifying parts of training syllabus.	Replace question: FROM: “What part of the training syllabus is assumed to be used in the context of the failure management?” TO: What pilot training assumptions (if applicable) are used in the context of the failure management?	Requested	Partially accepted.	As mentioned in paragraph 3.2, “It is recognized that the safety assessment is an iterative process. It is assumed that training syllabus might not be available or mature when the verification process is started, however the assumptions will need to be reconsidered based on the evolving maturity of the training syllabus.

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281	EMBRAER S.A.	Table 1	7	In “4. Flight crew response”, for the question related to temporal constraints in “Failure case#2”, the absolute definition of time has been shown impractical and there is currently no acceptable basis to define the time. Time is being used in a relative basis for defining prioritization among the conditions. Also, it is not practical to separate the time for flight crew perception, information processing and response. For assumptions about time, it is expected that experts judgment between manufactures and certifications authorities is commensurate with the failure classification.	Remove the question about time “What are the temporal constraints if any?”.	Requested	Not accepted.	See EASA answer to comment #279.
282	EMBRAER S.A.	Table 1	7	In “5. Post failure management”, the term “deferred item” is a nomenclature used in MMEL.	Replace “procedural deferred items” by “inoperative items”.	Recommended	Not accepted.	“Procedural deferred items” is used by EASA in this CM to deal with procedure steps that need to be addressed by the crew at a later stage (i.e.: other phase of flight). It is therefore not the same as “inoperative items”.
283	EMBRAER S.A.	Table 1	7	In “5. Post failure management”, the term “unusual” is not clear. It is requested to maintain consistency between this term and AMC 25.1309 for failure severity classification (Cat/Haz/Maj/Min/Nse).	Since it is expected that the present CM be replaced by regular rulemaking activity, this new activity must assure consistency with existing regulatory material (For example: AMC 25.1302 and AMC 25.1309)	Requested	Noted.	
284	TCCA - NAC	Table 1	p.7/11	Workload considerations are currently only reflected under item 5 (post failure management) of the table. However overall workload at the time of failure occurrence (multiple indications and flight deck effects, or other tasks to be performed) could also play a significant role in the crew’s ability for effective and timely perception, processing and response.	Workload considerations should be added as required under items 2-3-4 of Table 1.	Requested	Accepted	Workload aspects have been added to item 4 of table 1.

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285	TCCA - NAC	Table 1	p.7/11	<p>“Does the post failure situation imply application of unusual force on the flight controls?”</p> <p>TCCA concurs the crew’s physical ability to manage the failure is also a critical parameter which needs to be considered and subsequently validated. Unusual forces on flight controls would be one example, but not necessarily the only one (e.g. ability to deal with smoke in the cockpit, etc). Also this consideration is not limited to post failure management, but could also be related to the expected immediate crew response to the failure (e.g. short term forces vs long term forces, using the flight controls example).</p>	<p>Recommend rewording as follows under item 5 (and adding as required under item 4):</p> <p>“Does the post failure situation imply <u>unusual physical demands on the crew (e.g. application of unusual force on the flight controls)</u>?”</p>	Requested	Accepted	Forces aspects have been added to item 4 of table 1.
286	Collins Avionics	Table 1	7	<p>The use of the term “Failure Case #1” and Failure Case #2” is a misnomer. These are not failure cases but information for the flight crew to recognize failures of the system. It may be clearer to state these in terms of Flight Crew recognition strategies.</p>	<p>Update “Failure Case#1:” and “Failure Case#2:” to something like, “Flight Crew Failure Recognition Case #1”, “Flight Crew Failure Recognition Case #2”.</p>	Recommended	Not accepted.	From EASA perspective, the first step to be accomplished is to define for each failure condition if it belongs to the Case #1 or Case #2. Hence, EASA believes columns titles are appropriately reflecting the intent of the columns.
287	Collins Avionics	Table 1	7	<p>Item 2: Perception – Under “Failure Case#1”, third bullet, what is meant by “What is the classification of the alert...”? Is this in the context of CS 25-1322?</p> <p>The fourth bullet mentions, “...aural attributes...”, however would that not be part of the “Failure Case#2” column?</p>	<p>As CS 25.1322 reference to the third bulleted item.</p> <p>Confirm intent of the aural attribute in the fourth bullet.</p>	Recommended	Partially accepted.	Reference to CS and AMC25.1322 has been added to clarify the intent of the question.
288	Collins Avionics	Table 1	7	<p>Item 4 Flight crew response: Under “Failure case#1”, for the first bullet, while Collins understands the intent, the training syllabus may not be formally available when the validation/verification results of the assumptions are due in the general process (especially for new aircraft or newer functions). The wording also states “...is assumed to be used...”, which further complicates if one is to state another assumption, and if so, what validation/verification is required.</p> <p>This wording is also present in other bulleted items.</p>	<p>Clarification needed on the intent of the highlighted items and what validation is necessary for the items stating more assumptions...</p>	Recommended	Noted.	As mentioned in paragraph 3.2, “It is recognized that the safety assessment is an iterative process. It is assumed that training syllabus might not be available or mature when the verification process is started, however the assumptions will need to be reconsidered based on the evolving maturity of the training syllabus.

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289	Collins Avionics	Table 1	7	Item 4 Flight crew response: Under “Failure case#2”, for the first bullet, this reads like an operational procedure. Seems like this should be similar to “Which procedure(s) is(are) assumed to be used?” under Failure case #1”.	Possibly reword to “Which procedure(s) is(are) assumed to be used?” under Failure case #1”.	Recommended	Accepted.	“Which procedure(s) is(are) assumed to be used?” has been added to case #2 item #4.
290	Collins Avionics	Table 1	7	The FHA should be agnostic to the system architecture Is this task part of FHA, the PSSA/SSA, or neither process ? Many questions contain elements that are part of the detailed design or may not be part of a certification package scope (e.g. training manuals). It is difficult understand what the expectations are for FHA validation especially during early stages of design. Stating this as an iterative process does not provide sufficient guidance for what is expected validation of the FHA and design matures. For example, it is unreasonable to expect the FHA to be validated with respect to the training materials during the preliminary design stages.	Clarify the intent of the task analysis within the wider scope of a development, with emphasis on what the requirements/ expectations are at various stages of design maturity and for variations of certification scope.	Requested	Noted	EASA recognizes that some assumptions cannot be validated during preliminary design phases. Nevertheless the expectations at various stages of design are not intentionally defined to give the applicant the possibility to propose its own process.
291	Collins Avionics	Table 1	7	The last three bullets state “unusual workload, unusual concentration, unusual force”. “Unusual” in this context is not clear and needs to be better defined or a more common term needs to be used. “Unusual” would infer some workload reference.	Replace “Unusual” with “Excessive” or defined “Unusual” in Section 1.4. Does it mean “Very high with no spare capacity” or “Task abandoned”.	Requested	Not accepted.	EASA intent is for the applicant to report levels (concentration, force or workload) that are not usual in the operation of the aircraft. These levels will be later assessed for their acceptability (excessive, unacceptable...), nevertheless EASA is targeting a delta in workload, concentration, force compared to before failure situation.
292	Collins Avionics	Table 1	7	The document needs to be clearer about what the result of this task analysis is and how it ties to the overall process.	Suggest including information regarding exactly what the objectives and the output of the task analysis should be and how the result fits into the overall process. Specifically, how it aids in the next step of determining "level of scrutiny".	Recommended	Not accepted.	The task analysis framework is intended to describe the kind of information that are requested and that allow the authority to make its own assessment of the degree of confidence that should be given to the assumptions made by the applicants about flight crew behaviours. This is deemed to be explained with the proper level of details and rationale in the CM.

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293	Collins Avionics	Table 1	7	Throughout this table the word “failure” is used but it is not clear what the intention is for the level of assessment of these “failures”. It is unclear if the intention is to assess each of these items per “failure condition” or per “failure mode”.	Define the usage of the word “failure” within this table or otherwise update the term in Table 1 to identify the level of assessment expected.	Recommended	Noted	Generic terms are used to adapt several processes.
294	Collins Avionics	Table 1	7	<p>It is not clear if the order of items within each block of the task analysis model align with what would be an appropriate approach for a process that complies to this guidance. (i.e.. Are these items ordered in a chronological order of the factors that help validate the FHA criticality or ordered according to another strategy?)</p> <p>The order of questions in Table 1 should follow a logical order congruent to the objectives of the Task Analysis which may be appropriate as is. However, the objectives of the task Analysis itself is unclear as noted by Comment 12 above.</p>	<p>Suggest that the ordering of items within each of Table 1’s categories maintain a logical flow according to the objective of the Task Analysis Model. If these items are intended to be coupled as part of the FHA process, ordering chronologically or by order of highest risk of severity elevation may be most appropriate. If coupled as part of an operational evaluation, reversing of the order could be appropriate.</p> <p>The agency’s philosophy behind the Task Analysis Model should be made clear to facilitate an applicant’s ability to produce an acceptable process.</p>	Requested	Not accepted.	This CM aims at providing a framework to the applicant for analysing the assumptions made with regards to flight crew behaviour within ASFHA. This framework can be adapted, detailed by applicant in order to be proposed to the EASA at project level. Hence should Collins wish to adapt the order of items to better reflect Collins’ logical flow, such proposal can be made at the next project where this CM will be applicable.
295	GE Aviation – Human Factors	Table 1	7	The description of Failure Case #2 is unclear as to whether all of these heterogeneous symptoms are tested at the same time, if it is a mix, or if it is one at a time.	Add language in the preceding paragraph to clarify the scope/nature of this failure case.	Recommended	Not accepted.	The symptoms are not intended to be tested, but comprehensively described by the applicant so that the authority can have a clear understanding of them.

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296	GE Aviation – Human Factors	Table 1 – 2.0 Perception	7	The use of “observable” could be up for interpretation. It is critical that the primary failure is identified, particularly in complex scenarios.	Modify wording from “What is the primary failure and how is it observable by the flight crew?” to “What is the primary failure and how is it identified by the flight crew?”	Recommended	Not accepted.	From EASA perspective, initial failure identification is already an outcome of an information processing. At this stage of the table 1, EASA aims at gathering information on information that is observable to the crew. Identification would come later following flight crew reasoning.
297	GE Aviation – Human Factors	Table 1 – 2.0 Perception	7	What assumptions are being used with “the maximum period of time within which the crew is assumed to detect the alert?”? Is this assuming worst case scenario? Several factors will impact the pilot’s ability to detect/perceive an alert (e.g., fatigue, stress, startle effect) and should be considered in the assumption of maximum time. Careful consideration should be placed with regard to assumptions surrounding how long it will take for a pilot to detect an alert.	Add clarifying language regarding the assumptions used in determining the maximum period of time the crew would detect the alert.	Recommended	Noted.	It is not clear for EASA what is GE Aviation concern with this comment. EASA considers that the notion of time or delay within which the flight crew is assumed to detect the alert and/or flight deck effects is necessary to be listed as it could heavily impact the validity of the assumption made with regards to flight crew behaviour.
298	GE Aviation – Human Factors	Table 1 – 2.0 Perception	7	All possible sequencing orders should be considered to account for how this could alter the pilot's perception of the issue. Will all potential sequences be tested?	Add follow-on question if different sequencing orders for these effects may alter the flight crew’s perception?	Recommended	Not accepted	The sequencing of flight deck effects is deemed relevant for the case 2 only. The comment is already answered thanks to the following text: “In which order do all those effects appear?”
299	GE Aviation – Human Factors	Table 1 – 4.0 Flight crew response	7	The use of memory items increases the risk for error and conducting procedures from memory should be discouraged. The use of recognition through aides or checklists versus using recall would be preferred in a failure/emergency scenario.	Add additional question of “Which aides or checklists are assumed to be used, if any?”	Recommended	Noted.	The fact that the use of memory items is challenging is precisely the reason for which this CM requires the applicants to indicate where memory items are assumed to be used, so that the authority can properly assess the validity of the assumptions made by the applicants on flight crew behaviours.

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300	GE Aviation – Human Factors	Table 1 – 4.0 Flight crew response	7	The procedure also needs to be binary/unambiguous to reduce errors in decision-making.	Add additional question of “Are the assumed procedures binary/unambiguous?”	Recommended	Not accepted.	They aim of the table 1 is to list information considered necessary by EASA to analyse the assumptions made with regards to flight crew behaviour for each failure condition. The assessment of such information for being clear, unambiguous etc, is part of the required evaluation to be done by the multidisciplinary team of experts. Hence it is not intended to be presented in the table 1. Finally, it is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason,
301	GE Aviation – Human Factors	Table 1 – 4.0 Flight crew response	7	Basic airmanship skills have become more degraded with increased reliance on automation. Is the crew transitioning from an automated system to manual flying? The difficulty of using basic airmanship for the pilot should be considered as well and the recency/training of the assumed basic airmanship.	Reword question from “Is the flight crew expected to use basic airmanship?” to “Is the flight crew expected to shift from using an automated system to basic airmanship/manual flight? Is the flight crew proficient in the assumed basic airmanship task?”	Recommended	Not accepted.	EASA intention is not to capture the transition from an automated flight to a manual flight, but to rather capture skills and or basic pilots’ know-how that applicant consider to be used by the flight crew to deal with the situation. Hence, the current wording is considered appropriate by EASA. Furthermore, the CS25 assumes flight crews that are properly trained and proficient. The fact that a failure condition requires pilots to transition from automated operations to manual flying is likely to bring questions that may decrease the level of confidence in the validity of the assumptions, on a case-by-case basis. However, the proficiency of flight crews cannot be part of the kind of information requested by the authority to assess the validity of assumptions.
302	GE Aviation – Human Factors	Table 1 – 4.0 Flight crew response	7	For complex scenarios involving multiple indications/failures/etc., going from memory should be discouraged due to its fallible nature and increased likelihood of error.	Add additional question of “Which aides or checklists are assumed to be used, if any?”	Recommended	Accepted.	Check lists added in the text.

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303	GE Aviation – Human Factors	Table 1 – 5.0 Post failure management	7	The use of the term “post failure management” sounds as though the failure has been resolved and is over, but the questions read like how the pilot manages the active failure. "Post" is confusing if the section is referring to the pilot managing the failure mode.	Change verbiage of “post failure management” to “failure management”	Recommended	Not accepted.	Table 1 part # 5 is actually dealing with post failure management, not current failure management. The questions aim at addressing the consequences of the failure on the rest of the flight. Some of the questions have been re-written to clarify the scope.
304	GE Aviation – Human Factors	Table 1 – 5.0 Post failure management	7	As our systems are becoming more complex, human system integration is becoming more important. How the failure condition impacts other aircraft systems/functioning should be an important consideration for the consequences of the failure condition beyond being inoperative or unavailable.	Add verbiage in the “etc” of “impacts to integrated systems/functioning”	Recommended	Not accepted.	The impacts of the initial failure to the integrated systems/functioning are actually intended to be covered by the cascading effects.
305	GE Aviation – Human Factors	Table 1 – 5.0 Post failure management	7	“Operational limitations to be respected” is unclear. What is this referring to?	Add an e.g., to list examples of what the operational limitations are referencing	Recommended	Accepted	Examples have been added “What are the operational limitations to be respected due to the failure (e.g.: altitude, speed, temperatures...)?”
306	GE Aviation – Human Factors	Table 1 – 5.0 Post failure management	7	If procedures were deferred, why? Is that standard/normal?	Add additional question of “If yes, then why were procedures deferred?”	Recommended	Not accepted.	Comment is not understood by EASA. As part of a procedure, some items may need to be deferred to a later phase of flight as a consequence of the failure, these items to be accomplished later are the ones to be described here.
307	GE Aviation – Human Factors	Table 1 – 5.0 Post failure management	7	For “manual actions of the flight crew”, consider also looking at the actions of automation and how that can factor into actions of the flight crew and its associated feedback, whether it is helpful or creates additional barriers.	Add additional question of “What additional actions are accomplished by automated systems during the failure? Do the automated functions impede flight crew actions?”	Recommended	Not accepted.	See EASA answer to comment #260.

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308	Merlin Labs	Table 1 Task 2, Perception	7	Recommend rewording of the “Perception” item to match 3.1 section wording. They are perceiving the failure condition and their response may result in further effects.	Replace “Perception (by the flight crew of flight deck effects)” with “Perception (by the flight crew of the failure indication(s))”	Requested	Not accepted.	“Flight deck effects” are not necessarily resulting from flight crew response and can also be part of the perceivable elements that can help the crew detecting the initial failure.
309	Boeing	Table 1, Failure case#2: definition	7	“Primary failure” is not defined.	Boeing requests that EASA define “primary failure”. Suggest change to “functional failure condition”.	Requested	Partially accepted.	The term “partially” has been replaced by “initial”, which makes it more explicit.
310	ANAC	Table 1, Flight crew response	7	Table 1, Flight crew response: the question “What part of the training syllabus is assumed to be used in the context of the failure management?” listed under Failure case #1 seems to also apply to Failure case #2. In fact, it could be argued that this question is even more important for failure case #2, where greater diversity of scenarios, multiple alerts and procedures, are expected.	Consider replicating the referenced question as applicable for both failure cases as suggested in the comment.	Recommended	Accepted.	Text added.
311	Collins Avionics	Table 1, Header row, 2nd Column	7	Failure case #1 explicitly calls out “alert from the Crew Alerting System (CAS)”. However there are other ways to get time-critical, specific alerts to the crew besides CAS messages, such as PFD flags, EIS flags, stall horn, stick shaker, TAWS/TCAS Aural, Unusual Attitude arrows, airspeed tape colouring (barber pole), etc. There are also specific alerts that are less time critical like FMS alerts.	Failure case #1 should be reworded to allow for these other ways of alerting the crew besides just CAS messages. I suggest removing the words “from the Crew Alerting System (CAS)” from the header. The header would then become “Explicit alert unambiguously pointing to the primary failure”	Requested	Not accepted.	All the objects described in this comment are part of the Crew Alerting System, apart from the FMS messages, that are not intended to be alerts (and generally they do not have to comply with CS 25.1322).

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312	TCCA - NAC	Table 1, item 2, FC#1	7	Under failure case #1, bullet three, the text reads: “what is the classification of the alert used to inform the crew of the failure”? Does this mean the alert level (e.g. warning, caution, advisory), or the type of alert (e.g. visual, aural, tactile), or the failure condition classification (e.g. catastrophic, hazardous, major)?	Suggested rewording: What is the classification of the alert used to inform the crew of the failure (i.e. warning, caution, advisory)?	Recommended	Accepted	See comment 20
313	TCCA - NAC	Table 1, item 2, FC#1	7	Under failure case #1, bullet four, the text reads: “How does the alert appear (location of the visual cues, number of modalities used, graphical and/or aural attributes and characteristics)?	Suggested Wording. What kind of alert(s) is used (e.g. visual, aural, tactile) and how does it appear (e.g. location, number of modalities used, characteristics of the alert).	Recommended	Accepted.	. Text modified accordingly
314	ANAC	Table 1, Post failure management	7	ANAC understands that the last three questions related to unusual workload, concentration, and force on the flight controls are applicable to both post failure management as well as flight crew response. Those aspects are expected to be relevant during failure response, which effectiveness can be affected by workload, concentration and force. Post failure management is usually related to an already controlled and stable situation, but that can also be affected by workload, concentration, and force .	Consider adding the questions related to unusual workload, concentration, and force on the controls also in the step 4 (flight crew response).	Recommended	Accepted.	Text modified accordingly
315	Boeing	Table 1, Step 2, column 2	7	The CM States: “What is the classification of the alert used to inform the crew of the failure?” Boeing would like to note the need to define "classification." Does “classification” refer to warning/caution/advisory?	Please provide the definition as “classification (WARNING, CAUTION, ADVISORY)”	Requested	Accepted	Definition added in 1.4.
316	FAA AIR-633	Table 1, task model 2	7	“What is the comprehensive list of secondary failures that are triggered?” Here should it be secondary indications? typically there is no secondary failure unless this a system level failure or cascading type of failure due to the primary failure.	“What is the comprehensive list of secondary indications that are triggered?”	recommended	Accepted	Text has been reworded.

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317	FAA AIR-633	Table 1, task model 3	7	“How is the crew assumed to prioritize the secondary effects to be dealt with?” Secondary indications to be included in this list	How is the crew assumed to prioritize the secondary effects and indications to be dealt with?	recommended	Accepted	Text reworded
318	FAA AIR-633	Table 1, task model 3	7	Post Failure management All task models are for post failure management so why is this called out uniquely?	Either delete this task model or name it as post failure management summary/analysis which will include all the above task models into consideration during the analysis	Requested	Not accepted	Not sure to understand the question. That’s true that the entire table 1 refers to things happening after the failure occurrence. The row 5 is intended to address the long-term consequences of the failure on the remaining on the flight once the failure itself is managed.
319	Boeing	Table 2	10	The method for “very high degree” is expert judgment. This is not consistent with the deliverable which is seeking applicable evidence.	Boeing requests that EASA replace “Summary of cases supported by applicable evidence” with “Summary of cases supported by applicable documentation of review.”	Requested	Partially accepted.	Sentence already modified as follow: Summary of cases characterized and stated by the review team as “very high degree of confidence.
320	FAA AIR-710	Table 2	10	Table 2 uses the term “expert”. How does EASA define and expert?		Requested	Noted	“Expert judgment” has been replaced by “Engineering judgement”.
321	FAA AIR-710	Table 2	10	Table 2 requires (under deliverables) a “summary of cases supported by applicable evidence”. How is this deliverable quantified?		Requested	Not accepted	Quantified? Question is not understood.
322	FAA AIR-710	Table 2	10	Table 2 states (under methods), “expert judgement supported by additional data”. How is “additional data” quantified? See “expert” question above.		Requested	Not accepted.	Same as previously. I guess the question is about “what are the expected deliverables”. Do we need to specify? (Minutes of meetings, of reviews, etc)? Question is not understood. In any case, EASA considers that subjective data is considered here.

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323	Bombardier	Table 2	10	“Complex tools and methods (simulator, aircraft, scenario-based approach) in addition to analysis and engineering judgement.” Should include "test bench" to be consistent with the next paragraph.	Rephrase as “(test bench, simulator and aircraft)”	Requested	Accepted	Accepted.
324	Bombardier	Table 2	10	“Complex” in "Complex tools and methods" is not explicit; should be replaced by either "Human Factors" or "User Centered" tools and methods.	Replace “Complex” by “Human Factors” or “User Centered” tools and methods.	Requested	Partially accepted.	The proposals are not in line with the initial intent. However, EASA replaced “complex” by “advanced”.
325	Bombardier	Table 2	10	“Complex tools and methods (simulator, aircraft, scenario-based approach)...” Application of a “full” Human Factors process should not automatically involves a scenario based approach if other suitable human in the loop evaluation can be performed.	Replace “scenario-based approach” by “human in the loop based approach”	Requested	Not accepted.	Scenario-based approach is the wording that has been adopted by EASA and is considered equivalent to “human in the loop-based approach”. Should be kept for consistency purpose with other EASA regulatory material.
326	Garmin	Table 2	10 of 11	The methods of determining the "level of confidence" as elaborated in the Table 2 Methods column seem to be very loose and broad, and, therefore, subject to very inconsistent interpretation and application. In particular, what constitutes "expert judgement"?	Request that more objective criteria be developed to assist applicants in determining the level of confidence.	Requested	Partially accepted	It is on purpose that the material is intended to be non-prescriptive. EASA is willing to let the applicants develop their own process and criteria. For that reason, EASA will not comply with the request to define more specific criteria. The wording “expert judgement” is replaced by “engineering judgement” which is less ambiguous.
327	EMBRAER S.A.	Table 2	10	It is not clear the criteria for defining the “confidence degree”. However, AMC 25.1302 also contains criteria for defining level of scrutiny during the certification process. Instead of defining a new criteria for driving the level of scrutiny for assumptions validation based on confidence degree, use the existing criteria on AMC 25.1302.	Reference the criteria on AMC 25.1302 for defining the level of scrutiny for assumptions validation.	Recommended	Not accepted.	The determination of the level of scrutiny in 1302 is not strictly equivalent to what is proposed here. It may confuse the applicants.
328	Collins Avionics	Table 2	10	Very high degree of confidence row, under Deliverables column, it is not clear what “Summary of cases” are in context of “Expert Judgement Only”. “Cases” is not clear in terms of what this is exactly. Are these the list of failure conditions with supporting evidence?	“Summary of Failure Conditions supported by applicable evidence”	Recommended	Accepted	It refers to the failure case analysed in table 1. These can be part of one or multiple failure conditions.

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329	Collins Avionics	Table 2	10	<p>For “All other Cases” row, under the “Means” column, is there an expectation that all methods are needed? If the assumption can be sufficiently verification/validated by “test”, why then would analysis and engineering judgement also need to be used? This may provide decreasing value for high effort.</p> <p>Does “engineering judgement” mean the same as “expert judgement” as noted in the “Verify High degree of confidence” row or is that a term from ED79A/ARP4754A?</p> <p>Is “Complex” a requirement? This infers that tools need to be complex, which does not seem this was the intent.</p>	<p>“Conformed validation/verification environments (simulator, aircraft, scenario-based approach). Additional methods such as analysis and/or expert judgment may also be required.”</p> <p>Suggest using “expert judgement” instead of “engineering judgement” if the intent of the word choice is the same.</p> <p>Remove or reword “Complex” or otherwise clarify/define what complex tools/methods are.</p>	Requested	Not accepted.	<p>From EASA perspective, for the “all other cases”, it is possible that engineering judgement is supported by tests using advanced tools and methods, hence “means” column could then include both tests and analysis and engineering judgement.</p> <p>“Expert judgement” has been replaced by “engineering judgement”.</p> <p>“Complex” has been replaced by “advanced”.</p>
330	Boeing	Table 2 first row	10	<p>More clarification is needed or specification for what crew actions or types of crew actions can fall into each category. The criteria that distinguish between “Very High Degree” and “High Degree” are ambiguous in this CM and may be difficult to define.</p>	<p>Boeing requests that EASA add: “Applicant should document how they determine “Very High Degree” and “High Degree” and coordinate with the regulator for concurrence.”</p>	Requested	Not accepted.	<p>Paragraph 3.2 states “This categorisation process should be adequately documented and presented, and that the outputs of this process should be provided to the authority.”, which is considered covering the concern highlighted by Boeing.</p>

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331	FAA AIR-710	Title referring to Regulatory Requirements	1	Regulatory Requirement(s): CS 25.1309(b) and (c): As defined by EASA, this CM is for two paragraphs of 25.1309. Why is 25.1302 used as part of the memorandum language for this rule? Is the intent for the System Safety Assessment process to include 25.1302 in their process?	Clarification within CM	Requested	Accepted	The scope of the CM is CS 25.1309(b) and (c). The data and activities generated as part of 25.1302 compliance demonstration may be used to validate the classification of some Failure Condition and may therefore contribute to CS 25.1309(b) and (c). This Certification Memo and more generally the System Safety Assessment process does not aim to change 25.1302. To avoid confusion, CS25.1302 quotes have been removed.
332	TCCA - NAC	Title, 1.1 and 2.1	1, 3, 4.	<p>FHA cases may be validated by analysis, simulation, test, etc. depending on the specifics of each scenario. FHA validation should start early and then be updated as designs refine and additional methods are available (e.g. simulators, test rigs). For many cases, it may not be possible to validate the specific FHA case. Instead, it may be necessary to inject failures that can represent the desired failure condition to assess the severity classification.</p> <p>This appears to be the crucial element where gaps occur. FHAs can be contentious, but it is often a borderline case (high end of major, low end of hazardous) where disagreements occur.</p> <p>The more contentious areas as noted by TCCA during recent certification programs, and illustrated in some accident investigations, is individual failure condition classifications. This is especially true for systems and/or items that interact with multiple systems. For example, an air data sensor may be initially tied to an FHA case for loss of airspeed, or loss of altitude. However, as the aircraft and systems are designed and evolved, this sensor(s) may feed into multiple different systems such that its failure can result in cascading effects across multiple FHA boundaries.</p> <p>The AF447 and more recent 737-MAX accidents had several compounding factors. These aircraft may not have had an FHA case for "loss of pitot" or "loss of AoA" that would consider the effects on all impacted functions and systems. Focusing on the FHA may miss these critical cases.</p>	TCCA suggests that the title and focus of this CM be changed from "Human Factors Considerations in Aircraft and Systems Functional Hazard Assessments" to "Human Factors Considerations in Failure Condition Classification"	Recommended	Noted	EASA agrees with TCCA understanding and share the same experience. The focus of the certification memo is indeed the failure condition classification. Some manufacturers may have safety assessment process which consider the cascading effects outside the scope of one individual FHA. It was however decided to align the title with the initial output of the CATA Task and ensure harmonisation to the maximum extend possible.

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333	HeliOffshore	Whole Document		<p>In considering the ‘total system’ approach, it can be helpful to imagine how we would approach the operator error issue if the operator were to be replaced by a robot pilot, that is, consider the reliability of the functions performed (remembering that trainee pilots have human performance exams where they will be taught that the general probability of human error is 10⁻³, yet it is not considered in the SSA). When we automate the operator function, to make it more reliable, the SSA then incorporates the failure rate, thus from the SSA viewpoint the automation makes the function less reliable.</p> <p>The functional analysis will look at a set of functions and the possible things that could go wrong with the function. Really that should look at equipment failures and human failures, and then the mitigations that the system can provide for the human failures as well as the mitigation is that humans can provide for system failures. This is an important way of thinking so that the manufacturers are not looking for humans to cover areas where they cannot make the design fully effective. Also getting them to think of how the system can better support people is very important.</p>	Consider the comments in the overall scope of the document	Recommended	Noted	
334	HeliOffshore	Whole Document		<p>This work is supported by HeliOffshore; we believe it addresses one aspect of the issue, but not the whole issue. Therefore, it is a positive step forward but does not fully integrate human error considerations into the SSA. We propose that the work should be expanded in order to address the wider spectrum of human error issues. This can be framed in such a way to target the most important areas and thus contain the scope of the activity to a manageable level. We have successfully applied this type of approach, and are very happy to assist further.</p> <p>Contributors to comments: Gretchen Haskins Hazel Courteney Simon Gill</p>	Consider amending the scope of the document as this will not require significantly more work by manufacturers, but it will make a major difference in the mindset during design and value of the work done during certification.	Requested	Noted.	Agreed that the proposed CM address only one aspect of the issue, but not the whole issue. The CM is part of a wider EASA initiative which include actions ranging from organization considerations, certification as well as continuing airworthiness aspects.

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335	ASD	Table 2	8	For very high degree of confidence cases, it is expected that characterizing the scenario as per table 1 is robust enough to support the conclusion. Therefore, a single statement declaring that it fits with this category should be sufficient. If further evidence is needed, that means that the scenario should belong to one of the 2 other categories (“high degree of confidence” or “all other cases”).	it is proposed to reword: “Summary of cases characterized and stated as “very high degree of confidence”	Requested	Noted.	Deliverables have been changed as follow: “Summary of cases characterized and stated by the review team as “very high degree of confidence”