

Notification of a Proposal to issue a Certification Memorandum

Analysis of occurrence reports and determination of possible unsafe conditions originated by human performance issues on large aeroplanes

EASA CM No.: CM-21.A-A-003 Issue 01 issued 16 June 2023

Regulatory requirement(s): Part 21.A.3A and 21.A.3B [AMC1 21.A.3B(b) and GM1 21.A.3B(b)]

EASA Certification Memoranda clarify the European Union Aviation Safety Agency'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 and do not constitute any legal obligation.

EASA Certification Memoranda are living documents into which either additional criteria or additional issues can be incorporated as soon as a need is identified by EASA.

1. Log of issues

Issue	Issue date	Change description
01	16.06.2023	First issue for public consultation.

2. Table of Content

1. Log of issues.....	2
2. Table of Content	2
3. Introduction.....	3
3.1. Purpose and scope	3
3.2. References	3
3.3. Abbreviations.....	4
3.4. Definitions	5
4. Background.....	6
4.1. Human Factors process in Initial Airworthiness	6
4.2. Limitations of the Initial Airworthiness process	6
5. EASA Certification Policy	7
5.1. Analysis framework	8
5.1.1. Step 1: Determine whether the reported event reveals a human performance issue	8
5.1.2. Step 2: Determine the cause of the human performance issue	9
5.1.3. Step 3: Determine whether a human performance issue is likely to lead to a possible unsafe condition 11	
5.2. Determination of an HF unsafe condition	11
5.3. Corrective actions for HF unsafe conditions	12
6. Who this Certification Memorandum affects.....	12
7. Remarks	12

3. Introduction

3.1. Purpose and scope

The purpose of this Certification Memorandum (CM) is to provide guidance to large aeroplanes Design Approval Holders (DAH) for analysing collected reports of and information related to in-service occurrences involving human interventions, either during operator's flight operations or during operator's simulator training, which has resulted or may result in unsafe conditions. Mandatory reporting to EASA of possible unsafe conditions determined to result from in-service occurrences with a human intervention is also an obligation for DAH under point 21.A.3A of Part 21 and part of the Continuing Airworthiness (CAW) activities for their products. The objectives of analysing such occurrences are therefore to identify flight crew behaviours occurring in-service that deviate from the assumptions made by the DAH when demonstrating compliance with the certification basis (IAW), and to assess the associated safety consequence. Thus, this CM provides material that complements the limited guidance currently existing in GM1 21.A.3B(b) for establishing if a condition originated¹ by human interventions on a large aeroplane is unsafe.

3.2. References

It is intended that the following reference materials be used in conjunction with this Certification Memorandum:

Reference	Title	Code	Issue	Date
[1]	Certification of aircraft and related products, parts and appliances, and of design and production organisations	Annex I (Part 21) to Commission Regulation (EU) No 748/2012	Latest amendment	03/08/2012
[2]	Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Annex I (Part 21) to Commission Regulation (EU) No 748/2012	ED Decision 2022/021/R	Issue 2, amendment 14	19/12/2022
[3]	Certification Specifications and Acceptable Means of Compliance for Large Aeroplanes	CS-25	Amendment 27	24/11/2021

¹ In this CM, the term "originated" refers to human interventions as either root cause or contributing factor to the reported occurrence.

3.3. Abbreviations

AD	Airworthiness Directive
AFM	Aircraft Flight Manual
AMC	Acceptable Means of Compliance
ATO	Approved Training Organisations
CAA	Civil Aviation Authority
CAW	Continuing Airworthiness of the approved design
CM	Certification Memorandum
CRM	Crew Ressource Management
CVR	Cockpit Voice Recorder
DAH	Design Approval Holder
EASA	European Union Aviation Safety Agency
FCOM	Flight Crew Operating Manual
FCTM	Flight Crew Training Manual
FDM	Flight Data Monitoring
GM	Guidance Material
HF	Human Factors
IAW	Initial Airworthiness
OSD	Operational Suitability Data
OSD-FC	Operational Suitability Data for Flight Crew
TC	Type Certificate



3.4. Definitions

Design Approval Holder	In the context of this CM, a DAH is meant to be the holder of a type-certificate, restricted type-certificate, supplemental type-certificate, or any other relevant approval deemed to have been issued under Part 21.
Flight crew	Licensed crew members charged with duties that are essential for the operation of an aircraft during a flight duty period.
Human error	A flight crew's action or inaction that may lead to deviations from what was assumed to be adequate flight crew behaviour at time of certification of a flight deck. Human errors may be of the following types: an inappropriate action, a difference from what is expected in a procedure for both normal and abnormal/emergency operational situations, an incorrect decision, an incorrect keystroke, or an omission.
Human factors	It is anything that affects human performance and which seek safe interface between the human and other system components by proper consideration of human performance (ref. ICAO Doc 10151 — Human Performance (HP) Manual for Regulators).
Human intervention	It refers to any action or inaction taken by a flight crew in operation that preceded the safety occurrence. It can belong to different categories such as perception, planning and decision making, response execution and communication.
Human performance issue	A deficiency or undesired outcome that affects human's ability to perform tasks as the result of various factors, including human interaction with the machine, the environment or other involved stakeholders. It can manifest in different ways, such as human errors, but also encompasses other kind of shortcomings, E.g. suboptimal strategies, difficulty in finding information, inappropriate levels of workload..etc, or may also include any other observable item that cannot be considered to be a human error, but still reveals a flight deck design, flight crew training or operational procedures-related concern
Risk assessment	It is an evaluation that is based on engineering and operational judgement and/or analysis methods in order to establish whether the achieved or perceived risk is acceptable or tolerable.



Suboptimal-strategies	Methods, processes or techniques that are considered being not ideal or efficient for a given task and may lead to errors, or decreased performance.
-----------------------	--

4. Background

4.1. Human Factors process in Initial Airworthiness

For the approval of the installed systems and equipment used by the flight crew in the flight deck of large aeroplanes, the applicant for certification must demonstrate compliance with the applicable human factors (HF) certification specifications², in order to anticipate potential in-service events related to human performance. For that purpose, the applicant for certification must ensure that the design of flight decks considers a comprehensive set of design principles.

Flight decks must be designed with the objective to prevent as much as practicable the occurrence of human errors while operating the aircraft in normal and abnormal operational situations, including in the event of aircraft systems failure conditions. In addition, the operational environment should allow for an effective management of human errors, should they occur despite the compliance of the flight deck with the applicable requirements.

4.2. Limitations of the Initial Airworthiness process

Certification or approval of a flight deck is a demonstration of compliance with HF-related requirements which are intended to ensure an acceptable level of safety. However, in service experience, additional testing, further analysis, etc., may show that certain initially accepted assumptions are not correct. Thus, certain conditions initially demonstrated as safe, are revealed by experience as unsafe.

To support the determination of a possible unsafe condition originated by human interventions, the investigation of the DAH requires proper analysis of the occurrence reported, which includes comparison with and reconsideration of the assumptions made about flight crew behaviours during the original certification. This analysis is expected to be done with meaningful analytical HF approach and methodology, aimed at understanding the reason(s) for human performance issues and, when confirming the unsafe condition, defining adequate mitigation means to be mandated as corrective action(s).

² Such as CS 25.1302 and the other system specific and generally applicable requirements



5. EASA Certification Policy

Without prejudice to Regulation (EU) No 376/2014, Part 21 requires each DAH to undertake the obligations laid down in points 21.A.3A and 21.A.3B.

Under point 21.A.3A, the DAH shall collect, investigate and analyse received occurrence reports of and information related to in-service events³ which cause or might cause adverse effects on the continuing airworthiness of the large aeroplane. The 'collection', 'investigation', and 'analysis' functions incumbent on the DAH are meant to: analyse events and related available information; identify adverse trend; the associated root cause(s); and determine any necessary corrective action (see AMC1 21.A.3A(a)). This requires to identify occurrences that have resulted or may result in an unsafe condition and to report them to the Agency. Therefore, the 'analysis' must ensure that reports and information sent, or available, to the DAH are fully investigated so that the exact nature of any in-service event and its effect on continuing airworthiness is understood. Then, under point 21.A.3B, this may result in corrective action(s) being mandated by an EASA airworthiness directive (AD) when an unsafe condition is confirmed to exist in the design of an aircraft.

This process equally applies to in- service occurrences originated by human interventions. In this regard, Sections 2.1.1 and 2.5 of GM1 21.A.3B(b) already provides some guidelines on HF aspects in establishing and correcting unsafe conditions. However, this Part 21 GM material is not always used in an appropriate way by DAHs and it deserves some clarification. For this reason, this CM has been developed to help them with additional guidance.

Thus, this CM is practical reference guidance for performing an in-depth analysis of received occurrence report of and information related to an in-service event originated by human interventions in order to determine:

1. If the event or condition reveals any human performance issues (e.g. deviation) with respect to the assumptions made/used by the DAH about the expected flight crew behaviour when demonstrating compliance with the applicable certification basis (IAW).
2. The root cause(s) of the human performance issue(s) identified, and
3. If the event has resulted or may result in an unsafe condition, which would then require mandatory reporting to the Agency and corrective action(s).

³ in this CM, the terms 'event' and 'occurrence' are used equally; they refer to safety relevant conditions encountered in service of which the DAH is aware.



5.1. Analysis framework

When such an in-service event involving human interventions is reported, it should undergo an in-depth HF analysis by the DAH in order to determine if it reveals any human performance issue, what is the root cause(s) of this human performance issue and if it may lead to a possible unsafe condition. This DAH analysis should first start by proactively collecting event-related data as relevant, available and reliable:

1. The narrative: accurate description of the reported event as coming from the collected occurrence source report, including all information relevant to the operation circumstances when the event occurred, such as the location, the weather conditions, the aircraft's systems configuration and flight phase, etc.
In addition, for training related event, the narrative should also include information on the representativeness of the training device (including its limitations), details on the scenarios flown and any element likely to bias the data collection;
2. Characterization of the reported event (details on the reported human intervention);
3. Characteristics of design elements that were intended to prevent or discourage incorrect operation;
4. The presence of indications or feedback that allowed the flight crew to detect an erroneous operating condition in both normal and abnormal operation situations;
5. Description of the existing means (i.e. design, procedures, training) which were intended to mitigate human performance issue, if any, or to reduce its operational consequences;
6. Information on the operational procedures used in the reported event;
7. Information on the Crew Resource Management (CRM);
8. Any useful information for the determination of the root cause(s) and contributing factor(s);
9. Any relevant data coming from the Flight Data Monitoring (FDM), Aircraft Communication Addressing and Reporting System (ACARS);
10. The existence of reports of similar previous HF occurrences, and whether or not they already resulted (on those occasions) in unsafe conditions;
11. The description of any reduction in the safety margins;
12. The subjective severity of the observed operational consequences.

5.1.1. Step 1: Determine whether the reported event reveals a human performance issue

The knowledge of the assumptions made/used during certification regarding what was considered to be expected normal, standard or acceptable (i.e. non deviating) flight crew behaviours in normal, abnormal and emergency operational conditions is an information basically held by the DAH.

Among all the reported events involving human interventions, DAH should identify those which constitute a deviation from the assumptions about the expected flight crew behaviour as



made/used at time of initial certification (IAW). In the context of this CM, any in-service events that constitute such a deviation are considered human performance issues.

5.1.2. Step 2: Determine the cause of the human performance issue

A human performance issue occurring during flight operation, may be due to a weakness in the design, in the operating procedures or in the training, or even a combination of the three. Establishing the root cause(s) of a human performance issue often requires an overarching view of the original occurrence and the circumstances that led to it. A too narrow focus on a single root cause may not properly reflect the complexity of a human performance issue and there is a risk that important aspects that must be considered to prevent reoccurrence could be missed.

Therefore, the DAH is expected to consider detrimental contributing factors, such as: flight crew communication breakdowns, lack of situational awareness, failure to follow standard operational procedures, lack of compliance with initial airworthiness assumptions and/or inadequate training and experience, flight crew fatigue, stress, distraction, and failure to follow established procedures, etc;

❖ Flight deck design-related human performance issues in operation

A design-related human performance issue is an in-service condition that may arise when a design element of a flight deck system or interface impairs the performance of the flight crew by hampering its ability to perform its tasks effectively and efficiently. The following list of examples is non exhaustive and aims at supporting the understanding of possible design-related human performance issues. As a general principle, attention should be paid to the fact that human performance issues could potentially be attributed to any design-related causes or a combination of several of them, such as:

- Slip in aircraft control actuation due to confusing and/or non-intuitive layout of its controls,
- Loss of situational awareness due to inadequate system(s) feedback following a flight crew action,
- Discomfort affecting the pilot concentration due to poor flight deck ergonomics,
- Slip in aircraft control actuation due to poorly and/or confusing labelling of its controls,
- Excessive workload due to information cluttering,
- Non detection of alert(s) due to information cluttering,
- Inadequate prioritization made by the flight crew of the information due to inappropriate Human Machine Interface characteristics
- Others ...



❖ **Flight crew operational procedure issues**

Flight crew behaviours that are not consistent with the assumptions made/used during initial certification of the flight deck may also result from issues related to the design of operating procedures. The following is non-exhaustive list of possible issues that may be revealed by unexpected flight crew behaviours, while facing normal or abnormal/emergency operational procedures:

- Inability for the flight crew to cope with the situation due to a missing procedure,
- Flaw in an existing procedure, E.g.:
 - Partial accomplishment of an abnormal procedure due to a missing step, in the procedure,
 - Mismanagement of the procedure due to poor procedural actions sequencing (e.g. deferred items not reminded to flight crew, flow of actions that are not consistent with the actual constraints of operation, etc.),
 - Procedural error due to incompatibility between an item of the procedure and the piece of flight deck design that is supposed to be used to accomplish the item. (e.g. lack of consistency between a control panel labeling and the text of the associated procedure),
 - Flight crew error due to poor human-machine interface characteristics of an electronic checklist.

❖ **Flight crew training issues**

Pilots training is performed in accordance with DAHs' documentation relating to aircraft operation and made available to Air Operators, Approved Training Organizations (ATO) and the trained pilots. This training documentation includes EASA-approved Aeroplane Flight Manuals (AFM) and Operational Suitability Data for Flight Crew (OSD-FC), and also other non-approved documents developed to support organizations in delivering pilots training, such as Flight Crew Operational Manual (FCOM) and/or Flight Crew Training/Technique Manual (FCTM). All these documents are basically used by Air Operators and Training Organizations to prepare their own training manuals and courses/programmes under the oversight of their Civil Aviation Authority (CAA).

In theory, the combination of well-designed aircraft flight deck and human-machine interfaces with adequate pilot training material (based on all available aircraft-relevant operational documentation), should ensure that the trained pilots will be perfectly qualified to safely operate the aircraft within the assumed operational envelope.

This is usually the case, but there may be cases, as described earlier in the CM, where flight crew behaviours are not always consistent with the assumptions made/used during certification of the flight deck, which may also be the consequence of inadequate training delivered to pilots of the aircraft.

Therefore, the DAH analysis should allow/ensure to assess whether these may have been caused by inappropriate pilot training. The following provides some examples of possible issues that can be revealed by inadequate flight crew training:



- Lack of understanding of system behaviour due to missing training
- Inconsistent application of normal and abnormal/emergency procedures
- Lack of understanding of the HMI and associated aircraft automation state and/or flight path

5.1.3. Step 3: Determine whether a human performance issue is likely to lead to a possible unsafe condition

The in depth analysis should enable the DAH to determine if an identified human performance issue has resulted in safety critical consequences, but may also potentially result in some if it had occurred in a different context with any predictable aggravating occurrence scenario derived from the original event. The most likely worst outcome of the identified human performance issue should be considered on the basis of a risk assessment. Practically, it is expected to assess and assign severity at aircraft level for the human performance issue scenario as it occurred under the raw condition of the original in-service event, and then, for any subsequent scenario in other conditions that could be reasonably predicted as possible worsening conditions. E.g. during another operational circumstance, or in combination with a deficiency in the aircraft, or both.

The conclusion of this analysis should allow DAH to determine if the reported in-service event may lead to a possible unsafe condition, the final objective being to decide whether corrective action is necessary or not in order to prevent repetition of a similar human performance issue in the future.

Possible unsafe conditions related to human performance issues must be reported by DAH to the Agency as per point 21.A.3A of Part 21 on the same basis as any failure, malfunction, defect or other occurrence that could affect the equipment and systems of a flight deck.

5.2. Determination of an HF unsafe condition

As per AMC1 21.A.3B(b), *“an unsafe condition exists if there is factual evidence (from service experience, analysis or tests) that:*

- (a) *An event may occur that would result in fatalities, usually with the loss of the aircraft, or reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be:*
 - (i) *A large reduction in safety margins or functional capabilities, or*
 - (ii) *Physical distress or excessive workload such that the flight crew cannot be relied upon to perform their tasks accurately or completely, or*
 - (iii) *Serious or fatal injury to one or more occupants**unless it is shown that the probability of such an event is within the limit defined by the applicable certification specifications, or*
- (b) *There is an unacceptable risk of serious or fatal injury to persons other than occupants, or*
- (c) *Design features intended to minimise the effects of survivable accidents are not performing their intended function.”*



The above definition is also applicable for the determination of an unsafe condition originated by human interventions. However, the clause *“unless it is shown that the probability of such an event is within the limit defined by the applicable certification specifications”* is not applicable to human performance issues, as the use of a probabilistic approach for these is usually considered not feasible. Instead, this following sentence should apply : **“unless, for an event originated by human interventions, it is shown that the means provided for the human performance issues’ prevention, detection and management are robust enough so that the likelihood of such an event is low.”**

Guidance on how to assess the robustness of prevention, detection and management means can be found in the AMC 25.1302.

5.3. Corrective actions for HF unsafe conditions

Under the requirement 21.A.3B(b), the Agency shall mandate corrective action(s) by means of an AD to restore an acceptable level of safety when an unsafe condition has been determined by the Agency to exist in an aircraft, as a result of a deficiency in the aircraft, or an engine, propeller, part or appliance installed on this aircraft. The same is applicable for a confirmed unsafe condition originated by human interventions. Apart from an aircraft design change, the corrective action may also consist of modifications to aircraft approved manual or OSD components, or a combination of some of them.

As the compliance time for an identified human performance related unsafe condition cannot be calculated quantitatively, the mandated compliance time should be conservatively based on engineering judgement supported by service experience data and the size of the affected fleet.

6. Who this Certification Memorandum affects

This CM applies to any large aeroplanes DAH.

7. Remarks

1. This EASA Proposed Certification Memorandum will be closed for public consultation on the **21 July 2023**. Comments received after the indicated closing date for consultation might not be taken into account.
2. For any question concerning the technical content of this EASA Certification Memorandum, please contact:
Name, First Name: **LABATUT, Mathilde**
Function: **Human Factors (HF) Expert**
Phone: **+49 (0)221 89990 6245**
E-mail: mathilde.labatut@easa.europa.eu

