**SORA ANNEX E: Integrity and Assurance Levels for the Operation Safety Objectives (OSO)**

[*1.* *How to use SORA Annex E* 2](#_Toc513097583)

[*2.* *Technical issue with the UAS* 3](#_Toc513097584)

[OSO #01 - Ensure the operator is competent and/or proven 3](#_Toc513097585)

[OSO #02 - UAS manufactured by competent and/or proven entity 4](#_Toc513097586)

[OSO #03 - UAS maintained by competent and/or proven entity 5](#_Toc513097587)

[OSO #04 - UAS developed to authority recognized design standards 6](#_Toc513097588)

[OSO #05 - UAS is designed considering system safety and reliability 7](#_Toc513097589)

[OSO #06 - C3 link performance is appropriate for the operation 8](#_Toc513097590)

[OSO #07 - Inspection of the UAS (product inspection) to ensure consistency to the ConOps 10](#_Toc513097591)

[*3.* *OSO #xx – Operational procedures* 11](#_Toc513097592)

[*OSO #08 - Operational procedures are defined, validated and adhered to (to address technical issues with the UAS)* 11](#_Toc513097593)

[*OSO #11 - Procedures are in-place to handle the deterioration of external systems supporting UAS operation* 11](#_Toc513097594)

[*OSO #14 - Operational procedures are defined, validated and adhered to (to address Human Errors)* 11](#_Toc513097595)

[*OSO #21 - Operational procedures are defined, validated and adhered to (to address Adverse Operating Conditions)* 11](#_Toc513097596)

[*4.* *OSO #xx – Remote crew training* 13](#_Toc513097597)

[*OSO #09 - Remote crew trained and current and able to control the abnormal and emergency situations (i.e. Technical issue with the UAS)* 13](#_Toc513097598)

[*OSO #15 - Remote crew trained and current and able to control the abnormal and emergency situations (i.e. Human Error)* 13](#_Toc513097599)

[*OSO #22 - The remote crew is trained to identify critical environmental conditions and to avoid them* 13](#_Toc513097600)

[*5.* *OSO #xx – Safe design* 14](#_Toc513097601)

[*OSO #10 - Safe recovery from technical issue* 14](#_Toc513097602)

[*OSO #12 - The UAS is designed to manage the deterioration of external systems supporting UAS operation* 14](#_Toc513097603)

[*6.* *Deterioration of external systems supporting UAS operation* 16](#_Toc513097604)

[OSO #13 - External services supporting UAS operations are adequate to the operation 16](#_Toc513097605)

[*7.* *Human Error* 17](#_Toc513097606)

[OSO #16 - Multi crew coordination 17](#_Toc513097607)

[OSO #17 - Remote crew is fit to operate 17](#_Toc513097608)

[OSO #18 - Automatic protection of the flight envelope from human errors 19](#_Toc513097609)

[OSO #19 - Safe recovery from Human Error 20](#_Toc513097610)

[OSO #20 - A Human Factors evaluation has been performed and the HMI found appropriate for the mission 21](#_Toc513097611)

[*8.* *Adverse Operating Conditions* 22](#_Toc513097612)

[OSO #23 - Environmental conditions for safe operations defined, measurable and adhered to 22](#_Toc513097613)

[OSO #24 - UAS designed and qualified for adverse environmental conditions (e.g. adequate sensors, DO-160 qualification) 23](#_Toc513097614)

[*9.* *Assurance levels definition for technical OSO* 24](#_Toc513097615)

# *How to use SORA Annex E*

The following table provides basic principles to be kept in mind while using SORA Annex E.

|  |  |  |
| --- | --- | --- |
|  | **Principle description** | **Additional information** |
| #1 | Annex E provides criteria to assess the levels of integrity and assurance of an Operation Safety Objective (OSO) proposed by an applicant. | The identification of the Operation Safety Objectives necessary for a given operation, are under the responsibility of the applicant. |
| #2 | Annex E is limited to providing criteria to assess the levels of integrity and assurance of an Operation Safety Objective. It does not cover the Level of Involvement (LoI) of the Competent Authority since other factors (e.g. the performance of the applicant) could play a role in the determination of this LoI. | Some groups (e.g. JARUS WG-7) might provide foreseen level of involvement for Competent Authorities (but this will not only depend on the level of robustness). |
| #3 | The level of integrity/assurance of an Operation Safety Objective could rely on more than one criterion, in which case, all applicable criteria need to be met in order to achieve a given level of integrity/assurance. |  |
| #4 | The “optional” cases defined in SORA Main Body Table 8 does not need to be defined in terms of integrity and assurance levels in Annex E. | All robustness levels are acceptable for the Operation Safety Objectives for which an “optional” level of robustness is defined in Table 8 “Recommended Operation Safety Objectives (OSO)” of the SORA Main Body V1.2. |
| #5 | When criteria to assess the level of integrity or assurance of an Operation Safety Objective rely on “standards” not yet available, the OSO needs to be developed in a manner acceptable to the competent authority. |  |
| #6 | Annex E uses intentionally non-prescriptive terms (e.g. suitable, reasonably practicable) to provide the flexibility for the competent authority and the applicant to evaluate what is necessary on a case-by-case basis. |  |

# *Technical issue with the UAS*

## OSO #01 - Ensure the operator is competent and/or proven

* *Contributing JARUS WG(s): WG2*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #01**  **Ensure the operator is competent and/or proven (e.g. ROC)** | Criteria | The applicant has knowledge of the UAS being used and has relevant operational procedures including at least: checklists, maintenance, training, responsibilities, and duties. | Same as Low. In addition the applicant has an adequate organization, a method of identifying, assessing, and mitigating the risks associated with flight operations, consistent with the nature and extent of the operations specified. | The applicant holds an Organizational Operating Certificate (e.g. ROC) or has a recognized flight test organization. |
| *Comments* | *N/A* | *N/A* | *N/A* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #01**  **Ensure the operator is competent and/or proven (e.g. ROC)** | Criteria | The elements requested for the level of integrity are addressed in the CONOPS. | A competent third party performs inspection prior to first operation. | Same as Medium. In addition, a competent third party checks recurrently the operator competences. |
| *Comments* | *N/A* | *N/A* | *N/A* |

## OSO #02 - UAS manufactured by competent and/or proven entity

* *Contributing JARUS WG(s): WG2*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #02**  **UAS manufactured by competent and/or proven entity (e.g. industry standards)** | Criteria | Manufacturing procedures cover at least:   * the suitability and durability of materials used, * material specification, * processes necessary to allow for repeatability and conformity within acceptable tolerances. | Same as Low. In addition manufacturing procedures cover at least:   * configuration control, * verification of incoming products, parts, materials, and equipment, * identification and traceability, * in process and final inspections & testing, * control and calibration of tools, * handling and storage, * non-conforming item control. | Same as Medium. In addition, the manufacturing procedures cover at least:   * manufacturing processes, * personnel competence and qualification, * supplier control. |
| *Comments* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* | | |

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| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #02**  **UAS manufactured by competent and/or proven entity (e.g. industry standards)** | Criteria | The declared manufacturing procedures are developed to a recognized adequate standard. | Same as Low. In addition, evidence is available that the UAS has been manufactured in conformity to its design. | Same as Medium. In addition:   * manufacturing procedures, * conformity of the UAS to its design and specification   are regularly checked through process or product audit by a competent third party(ies). |
| *Comments* | *N/A* | *N/A* | *N/A* |

## OSO #03 - UAS maintained by competent and/or proven entity

* *Contributing JARUS WG(s): WG2*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #03**  **UAS maintained by competent and/or proven entity (e.g. industry standards)** | Criteria | * The UAS maintenance procedures are defined and cover at least the UAS designer instructions and requirements. * The maintenance team (i.e. the personnel authorized to conduct maintenance on the UAS in line with the maintenance procedures) is defined. | Same as Low. In addition:   * the maintenance procedures take the form of a Maintenance Program; * maintenance team is competent. | Same as Medium. In addition the tools and materials used in maintenance tasks are in accordance with the UAS designer requirements (e.g. calibration, life-limit). |
| *Comments* | *N/A* | *N/A* | *N/A* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #03**  **UAS maintained by competent and/or proven entity (e.g. industry standards)** | Criterion #1  (Procedure) | * The maintenance procedures are documented. * The maintenance conducted on the UAS are document in a maintenance log *(1) (2)*. | Same as Low. In addition, the maintenance procedures are validated against a recognized standard. | Same as Medium. In addition, the maintenance procedures are validated by a competent third party. |
| *Comments* | *(1) Designer instructions and requirements may include description of maintenance action that needs to be logged*  *(2) The maintenance log may be requested for inspection by the approving authority or an authorized representative.* | *N/A* | *N/A* |
| Criterion #2  (Training) | The maintenance team training to maintenance procedures is self-declared (with evidence available). | * Maintenance syllabus includes the UAS designer instructions and requirements for maintenance. * The maintenance team has undergone initial training by the operator. | Same as Medium. In addition:   * The maintenance team training is recurrent, and * A competent third party checks the maintenance competencies of the person in charge of the UA approval for release to service. |
| *Comments* | *N/A* | *N/A* | *N/A* |

## OSO #04 - UAS developed to authority recognized design standards

* *Contributing JARUS WG(s): WG3*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #04**  **UAS developed to authority recognized design standards** | Criteria | The UAS is designed to design standards recognized adequate for a Low level of Integrity and the intended operation. | The UAS is designed to design standards recognized adequate for a Medium level of Integrity and the intended operation. | The UAS is designed to design standards recognized adequate for a High level of Integrity and the intended operation. |
| *Comments* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.*  *The mapping between the identified industry standards and the different levels of integrity will be established by JARUS based on the feedback provided by the NAAs.* | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #04**  **UAS developed to authority recognized design standards** | Criteria | The level of assurance of this OSO needs to be assessed considering the criteria provided in section 9. | | |
| *Comments* | *N/A* | *N/A* | *N/A* |

## OSO #05 - UAS is designed considering system safety and reliability

* *Contributing JARUS WG(s): WG3*

Contrary to OSO #10 and OSO #12, this OSO is not limited to the risk to exit the operation volume or cause a fatality.

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| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #05**  **UAS is designed considering system safety and reliability** | Criteria | The equipment, systems, and installations are designed to minimize hazards1 to the UAS in the event of a probable malfunction or failure. | Same as Low. In addition:   * Software (SW) and Airborne Electronic Hardware (AEH) whose development error(s) may cause or contribute to a hazardous or catastrophic failure conditions are developed to recognized adequate standards. * The strategy for detection, alert and accommodation of any failure, which would lead to a hazard. | Same as Medium. In addition:   * Major Failure Conditions are not more frequent than Remote; * Hazardous Failure Conditions are not more frequent than Extremely Remote: * Catastrophic Failure Conditions are not more frequent than Extremely Improbable. * SW and AEH whose development error(s) are developed to objectives of DO-178/DO-254 or equivalent standards. |
| *Comments* | *1The term “hazard” needs to be understood as a failure condition that relates to major, hazardous, or*  *Catastrophic* | *DALs for SW/AEH may be derived from JARUS AMC RPAS.1309 depending on the equivalent manned aircraft class.* | *Safety objectives for failure conditions and DALs for SW/AEH may be derived from JARUS AMC RPAS.1309 depending on the equivalent manned aircraft class.* |

| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of ASSURANCE** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #05**  **UAS is designed considering system safety and reliability** | Criteria | A Functional Hazard Assessment1 and a design and installation appraisal substantiating the minimization of hazard is available. | Safety analyses and SW/AEH Development Assurance activities in line with recognized adequate standards. | * Safety analyses based on standards recognized by authorities to support demonstration of compliance with equivalent manned aircraft 1309/2510 requirements. * Safety analyses and Development Assurance activities checked by a competent third party. |
| *Comments* | *1Severity of failures conditions is expected to be determined according to the definition provided for No Safety Effect, Minor, Major, Hazardous and Catastrophic Failure Conditions in JARUS AMC RPAS.1309.* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* | * *Safety Analyses Standards recognized by authorities vary from SAE ARP4761 to ASTM standards (e.g. F3201) depending on the equivalent manned aircraft class.* * *Part-23.1309/CS-23.1309 are respectively named Part-23.2510/CS-23.2510 since Part 23 at Amendment 64 and CS-23 at Amendment 5* |

## OSO #06 - C3 link performance is appropriate for the operation

* *Contributing JARUS WG(s): WG5*

1. For the purpose of the SORA and this specific OSO, the term “C3 link” encompasses:
   * the Command and Control (C2) link, and
   * any communication link required for the safety of the flight.
2. In order to correctly assess the integrity of this OSO, the applicant should identify:
3. The C3 links, including their performance and Radio Frequency (RF) spectrum usage.

Note: the specification (performance and RF spectrum) for C2 Link is typically included in the documentation provided by the UAS designer (e.g. UAS manual)

Note: the main parameters associated to the C2 Link performance (RLP) and the communication performance for any other communication link (e.g. RCP for communication with ATC) include, but might not be limited to:

* Transaction expiration time
* Availability
* Continuity
* Integrity

Refer to ICAO references for definitions.

1. The required C3 links performance necessary for the intended operation.
2. The RF spectrum usage requirements for the intended operation (including the need for authorization if required).

Note: Usually, countries publish the allocation of RF spectrum bands applicable in their territory. This allocation stems mostly from the International Communication Union (ITU) Radio Regulations but there might be national differences and specific allocations (including national sub-division of ITU allocations); this is the reason why the applicant should check the local requirements and requests authorization when needed. Some aeronautical bands (e.g. AM(R)S, AMS(R)S 5030-5091MHz) were allocated for potential use in UAS operations under ICAO scope, in principle falling under cat. C (“certified”), but which might also be used for some operations authorized under the specific category. It is also expected that other licensed bands (e.g. mobile networks) might also be authorized under the specific category; some un-licensed bands (e.g. ISM (Industrial, Scientific, Medical) or SRD (Short Range Devices)) might also be acceptable.

1. The environmental conditions that might affect the C3 links performance.

| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of INTEGRITY** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #06**  **C3 link performance is appropriate for the operation** | Criteria | * The applicant determines that performance, RF spectrum usage (1)(2) and environmental conditions for C3 links are adequate to conduct safely the intended operation. * The UAS remote pilot has the means to continuously monitor the performance of C3 to ensure the adequacy of that performance to the operation requirements (3). | Same as Low. | Same as Low. In addition the use of licensed *(4)* frequency bands for C2 Link is required. |
| *Comments* | *(1)  For a low level of integrity, unlicensed frequency bands might be accepted under certain conditions, e.g.:*   * *the applicant demonstrates compliance with other RF spectrum usage requirements (e.g. for EU: Directive 2014/53/EU, for US: CFR Title 47 Part 15 Federal Communication Commission (FCC) rules), for instance by showing that the UAS pieces of equipment are compliant with these requirements (e.g. FCC marking), and* * *the use of protection mechanisms against interference (e.g. FHSS, frequency deconfliction by procedure).*   *(3) The remote pilot has access at all times and in a timely manner to the relevant information on C3 affecting the safety of flight. For the operations requesting only a low level of integrity for this OSO, this could be limited to monitoring the C2 link signal strength and receiving an alert from the UAS HMI if the signal is becoming too low.* | *(2)  The use of licensed frequency bands might be necessary depending on the operation considered, although the use of non-aeronautical bands (e.g. licensed bands for cellular network) might be acceptable.* | *(4) This is ensuring a minimum level of performance and is not limited to aeronautical licensed frequency bands (e.g. licensed bands for cellular network). It is nevertheless expected that some of the operations may require the use of bands allocated to the aeronautical mobile service for the use of C2 Link (e.g. 5030 – 5091 MHz).*  *In any case, the use of licensed frequency bands needs to be authorized.* |

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| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #06**  **C3 link performance is appropriate for the operation** | Criteria | Refer to the criteria provided in section 9. | Evidence for required C3 link performance is produced in accordance with recognized standards. | Same as Medium. In addition evidence is checked by a competent third party. |
| *Comments* | *N/A* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* | *N/A* |

## OSO #07 - Inspection of the UAS (product inspection) to ensure consistency to the ConOps

* *Contributing JARUS WG(s): WG2*

This OSO deals with the conformity of the UAS being used during the operation with the UAS definition used to support the approval/authorization of the operation.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #07**  **Inspection of the UAS (product inspection) to ensure consistency to the ConOps** | Criteria | The remote crew performs pre-flight inspection to ensure the UAS is in a condition for safe operation and conforms to the approved concept of operations. | | |
| *Comments* | *The modulation of the level of robustness is achieved through the level of assurance (see table below)* | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TECHNICAL ISSUE WITH THE UAS** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #07**  **Inspection of the UAS (product inspection) to ensure consistency to the ConOps** | Criterion #1  (Procedures) | Pre-flight inspection procedure is documented. | Same as Low. In addition:   * The pre-flight inspection procedure takes into account manufacturer’s recommendations. * Pre-flight inspection is documented by filling-up checklists. | Same as Medium. In addition, the pre-flight inspection procedure has been validated by a competent third party. |
| *Comments* |  | *N/A* | *N/A* |
| Criterion #2  (Training) | The remote crew’s training to the pre-flight inspection procedure is self-declared (with evidence available). | * A training syllabus including pre-flight inspection procedure is available * Competency-based theoretical and practical training organised by the operator | A competent third party:   * Validates the training syllabus. * Verifies the remote crew competencies. |
| *Comments* | *N/A* | *N/A* | *N/A* |

# *OSO #xx – Operational procedures*

### *OSO #08 - Operational procedures are defined, validated and adhered to (to address technical issues with the UAS)*

### *OSO #11 - Procedures are in-place to handle the deterioration of external systems supporting UAS operation*

### *OSO #14 - Operational procedures are defined, validated and adhered to (to address Human Errors)*

### *OSO #21 - Operational procedures are defined, validated and adhered to (to address Adverse Operating Conditions)*

* *Contributing JARUS WG(s): WG1, WG2 and WG3*

1. While building the SORA HRM model, OSO were classified in generic categories (technical issue with the UAS, deterioration of external systems supporting the UAS operation, Human Error …). This was deemed necessary in order to be exhaustive in the identifications of the different OSO. But this resulted in the identification of OSO, whose robustness levels can be assessed as a whole. This is the case of the following OSO:
   * OSO #08 - Operational procedures are defined, validated and adhered to (identified for the generic category: “Technical issue with the UAS”)
   * OSO #11 - Procedures are in-place to handle the deterioration of external systems supporting UAS operation (identified for the generic category: “Deterioration of external systems supporting UAS operation beyond the control of the UAS”)
   * OSO #14 - Operational procedures are defined, validated and adhered to (identified for the generic category: “Human Error”)
   * OSO #21 - Operational procedures are defined, validated and adhered to (identified for the generic category: “Adverse Operating Conditions”)
2. The applicant needs to propose “operational procedures” appropriate for the specificities of the operation to be approved including the following elements:
   * Flight planning,
   * Pre and post-flight inspections,
   * Procedures to evaluate environmental conditions before and during the mission (i.e. real-time evaluation),
   * Procedures to cope with adverse operating conditions (e.g. what to do in case icing is encountered during the operation, when the operation is not approved for icing conditions)
   * Normal procedures,
   * Contingency procedures (to cope with abnormal situations),
   * Emergency procedures (to cope with emergency situations), and
   * Occurrence reporting procedures.
3. The “operational procedures” covers:
   * the deterioration of the UAS itself,
   * the deterioration of any external system supporting the operation (\*), such as systems used to:
     1. launch / take-off the UAS,
     2. make pre-flight checks,
     3. keep the UA within its operation volume (e.g. GNSS, Satellite Systems, Air Traffic Management, UTM).

(\*) External systems activated/used after the loss of control of the operation are excluded from this definition.

1. In order to help a proper identification of the procedures related to deterioration of external systems supporting the UAS operation, it is recommended to:
   * identify the “external systems” supporting the operation,
   * describe the deterioration modes of these “external systems” which would prevent maintaining a safe operation of the UAS (e.g. complete loss of GNSS, drift of the GNSS, latency issues, …),
   * describe the means put in place to detect the deterioration modes of the external systems/facilities,
   * describe the procedure(s) in place once a deterioration mode of one of the external systems/facilities is detected (e.g. activation of the Emergency Recovery Capability, switch to a Manual control …).

| **OPERATIONAL PROCEDURES** | | **LEVEL of INTEGRITY** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #08, OSO #11, OSO #14 and OSO #21** | Criterion #1 (Procedure definition) | * Operational procedures appropriate for the specificities of the operation to be approved are defined and cover at least the following elements:   + Flight planning,   + Pre and post-flight inspections,   + Procedures to evaluate environmental conditions before and during the mission (i.e. real-time evaluation),   + Procedures to cope with adverse operating conditions (e.g. what to do in case icing is encountered during the operation, when the operation is not approved for icing conditions)   + Normal procedures,   + Contingency procedures (to cope with abnormal situations),   + Emergency procedures (to cope with emergency situations), and   + Occurrence reporting procedures. * Normal, Abnormal and Emergency procedures are compiled in an Operation Manual. * The limitations of the external systems supporting UAS for safe operations are defined in an Operation Manual. | | |
| *Comments* | *N/A* | *N/A* | *N/A* |
| Criterion #2  (Procedure complexity which could jeopardize adherence to) | Operational procedures are complex and/or lead to a significant increase of workload of the remote flight crew and/or interactions with several entities (ATM…) | Operational procedures involve the remote pilot to take manual control1 when the UAS is usually automatically controlled. | Operational procedures are simple |
| *Comments* | *N/A* | 1 *This is still under discussion since not all UAS have a mode where the pilot could directly control the surfaces; moreover, some people claims it requires significant skill not to make things worse.* | *N/A* |
| Criterion #3  (Consideration of Potential Human Error) | Operational procedures are providing at minimum:   * a clear distribution and assignment of tasks * an internal checklist to ensure staff are performing their assigned tasks. | Operational procedures take considerations of human errors. | Same as Medium. In addition the Remote Crew1 receives a Crew Resource Management (CRM)2 training. |
| *Comments* | *N/A* | *N/A* | *1 In the context of SORA, the term “Remote crew” refers to any person involved in the mission.*  *2 CRM training focuses on the effective use of all remote crew to assure a safe and efficient operation, reducing error, avoiding stress and increasing efficiency.* |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **OPERATIONAL PROCEDURES** | | | **LEVEL of ASSURANCE** | | | | | |
| **Low** | | **Medium** | | **High** | |
| **OSO #08, OSO #11, OSO #14 and OSO #21** | Criteria | * Operational procedures are not validated against a recognized standard. * The adequacy of the operational procedures and checklists is declarative, except for the Emergency Procedures, which are tested. | | * Operational procedures are validated against recognized standards. * The adequacy of the Abnormal and Emergency procedures is proved through:   + Dedicated flight tests, or   + Simulation, provided that the representativeness of the simulation means is proven for the intended purpose with positive results. | | Same as Medium. In addition:   * A competent third party validates operational procedures/checklists, flight tests and simulations. * Any flight test performed to validate the operational procedures cover the complete flight envelope or be proven to be conservative. | |
| *Comments* | | *N/A* | | *N/A* | | *N/A* | |

# *OSO #xx – Remote crew training*

### *OSO #09 - Remote crew trained and current and able to control the abnormal and emergency situations (i.e. Technical issue with the UAS)*

### *OSO #15 - Remote crew trained and current and able to control the abnormal and emergency situations (i.e. Human Error)*

### *OSO #22 - The remote crew is trained to identify critical environmental conditions and to avoid them*

* *Contributing JARUS WG(s): WG1*

1. While building the SORA HRM model, OSO were classified in generic categories (technical issue with the UAS, deterioration of external systems supporting the UAS operation, Human Error…). This was deemed necessary in order to be exhaustive in the identifications of the different OSO. But this resulted in the identification of OSO, whose robustness levels can be assessed as a whole. This is the case of the following OSO:
   * OSO #09 - Remote crew trained and current and able to control the abnormal and emergency situations (i.e. Technical issue with the UAS)
   * OSO #15 - Remote crew trained and current and able to control the abnormal and emergency situations (i.e. Human Error)
   * OSO #22 - The remote crew is trained to identify critical environmental conditions and to avoid them.
2. The applicant needs to propose competency-based theoretical and practical training:
   1. appropriate for the specificities of the operation to be approved, and
   2. including the proficiency requirements and training recurrences.
3. The entire remote crew (i.e. any person involved in the operation) should undergo a competency-based theoretical and practical training specific to their duties (e.g. pre-flight inspection, ground equipment handling, evaluation of the meteorological conditions …).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **REMOTE CREW COMPETENCIES** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #09, OSO #15 and OSO #22** | Criteria | The competency-based theoretical and practical training should consist of the following elements:   * Basic competencies from the competency framework necessary to ensure a safe flight:   1. Application of operational procedures (normal, contingency and emergency procedures, flight planning, pre-flight and post-flight inspections…)   2. Communication   3. RPA flight path management, automation   4. Leadership, teamwork and self-management   5. Problem solving and decision-making   6. Situational awareness   7. Workload management   8. Coordination and handover * Familiarization with CAT B (Specific Category) * A rating training specific for the operation. | | |
| *Comments* | *The modulation of the level of robustness of this OSO is achieved through the level of assurance (see table below).* | | |

| **REMOTE CREW COMPETENCIES** | | **LEVEL of ASSURANCE** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #09, OSO #15 and OSO #22** | Criteria | Training is self-declared (with evidence available) | * Training syllabus is available * Competency-based theoretical and practical training organised by the operator | A competent third party:   * Validates the training syllabus. * Verifies the remote crew competencies. |
| *Comments* | *N/A* | *N/A* | *N/A* |

# *OSO #xx – Safe design*

### *OSO #10 - Safe recovery from technical issue*

### *OSO #12 - The UAS is designed to manage the deterioration of external systems supporting UAS operation*

* *Contributing JARUS WG(s): WG3*

1. While building the SORA HRM model, OSO were classified in generic categories (technical issue with the UAS, deterioration of external systems supporting the UAS operation …). This was deemed necessary in order to be exhaustive in the identifications of the different OSO. But this resulted in the identification of OSO, whose robustness levels should be assessed as a whole. This is the case of the following OSO:
   * OSO #10 - Safe recovery from technical issue (identified for the generic category: “Technical issue with the UAS”)
   * OSO #12 - The UAS is designed to manage the deterioration of external systems supporting UAS operation (Identified for the generic category: “Deterioration of external systems supporting UAS operation beyond the control of the UAS”)
2. Objective of these OSO is to address:
   * the risk for the UA to exit the operating volume, or
   * the risk to have a fatality because of a crash (when operating over high density population)

following failures of a UAS System or of any external system supporting the operation.

1. External systems supporting the operation are defined as systems not already part of the UAS but used to:
   * launch / take-off the UAS,
   * make pre-flight checks,
   * keep the UA within its operation volume (e.g. GNSS, Satellite Systems, Air Traffic Management, UTM).

External systems activated/used after the loss of control of the operation are excluded from this definition.

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| --- | --- | --- | --- | --- |
|  | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #10**  **& OSO #12** | Criteria | * No probable1 failure2 of the UAS or any external system supporting the operation leads to operation outside of the operation volume3. * It can be reasonably expected that a fatality will not occur from any probable failure of the UAS or any external system supporting the operation. | Same as Low but for any single failure3.  In addition:   * Software (SW) and Airborne Electronic Hardware (AEH) whose development error(s) could lead to operations outside of the operation volume or a fatality are developed to recognized adequate standards. * The strategy for detection, alert and accommodation of any probable failures is defined. | Same as Medium. In addition:   * The probability of operation outside of the operation volume4 or to have a fatality is extremely improbable5. * SW and AEH whose development error(s) could lead to operations outside of the operation volume or a fatality are developed to objectives of DO-178/DO-2545 or equivalent standards. |
| *Comments* | *1 The term “probable” needs to be understood in its qualitative interpretation, i.e. “Anticipated to occur one or more times during the entire system/operational life of an item.”*  *2 Some structural or mechanical failures may be excluded from the criterion if it can be shown that these mechanical parts were designed to aviation industry best practices.*  *3 Temporary excursions outside of the operation volume could be negotiated on a case-by-case basis* | *3 Some structural or mechanical failures may be excluded from the no-single failure criterion if it can be shown that these mechanical parts were designed to recognized adequate aviation standards* | *4 Temporary excursions outside of the operation volume could be negotiated on a case-by-case basis*  *5 Safety objectives / Development Assurance Levels might be derived from JARUS AMC RPAS.1309* |

|  | | **LEVEL of ASSURANCE** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #10**  **& OSO #12** | Criteria | A design and installation appraisal is available. In particular, the design and installation features (independence, separation and redundancy) allowing to meet the low integrity criteria are explained. | * Identification of the single failure of concern is done based on a Failure Modes and Effect Analysis (FMEA). * The strategy of detection of the single failure of concern include pre-flight checks. | * Safety analyses based on standards recognized by authorities to support demonstration of compliance with equivalent manned aircraft 1309/2510 requirements. * A competent third party checks the Safety analyses and Development Assurance activities. |
| *Comments* | *N/A* | *N/A* | * *Safety Analyses Standards recognized by authorities vary depending on the equivalent manned aircraft class from SAE ARP4761 “Guidelines and Methods for Conducting the Safety Assessment Process on Civil Airborne Systems and Equipment” to American Society for Testing and Materials (ASTM) standards, such as F3201* “*Standard Practice for Ensuring Dependability of Software Used in Unmanned Aircraft Systems”* * *Part-23.1309/CS-23.1309 are respectively named Part-23.2510/CS-23.2510 since Part 23 at Amendment 64 and CS-23 at Amendment 5* |

# *Deterioration of external systems supporting UAS operation*

## OSO #13 - External services supporting UAS operations are adequate to the operation

* *Contributing JARUS WG(s): WG5 (communication service provider) and WG3 (service provider other than communication)*

For the purpose of the SORA and this specific OSO, the term “External services supporting UAS operations“ encompasses any service provider necessary for the safety of the flight , e.g.

* + Communication Service Provider (CSP),
  + UTM service provider, …

| **DETERIORATION OF EXTERNAL SYSTEMS SUPPORTING UAS OPERATION BEYOND THE CONTROL OF THE UAS** | | **LEVEL of INTEGRITY** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #13**  **External services supporting UAS operations are adequate to the operation** | Criteria | The applicant ensures that the level of performance for any externally provided service necessary for the safety of the flight is adequate for the intended operation.  Roles and responsibilities between the applicant and the external service provider are defined. | | |
| *Comments* | *N/A* | *N/A* | *Requirements for contracting services with Service Provider may be derived from ICAO SARPS (currently under development).* |

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| --- | --- | --- | --- | --- |
| **DETERIORATION OF EXTERNAL SYSTEMS SUPPORTING UAS OPERATION BEYOND THE CONTROL OF THE UAS** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #13**  **External services supporting UAS operations are adequate to the operation** | Criteria | The applicant declares that the requested level of performance for any externally provided service necessary for the safety of the flight is achieved (without evidence being necessarily available). | The applicant has supporting evidence that the required level of performance can be achieved for the full duration of the mission.  This may take the form of a service-level agreement (SLA) or any official commitment that prevails between a service provider and the applicant on relevant aspects of the service (including quality, availability, responsibilities).  The applicant has a means to monitor externally provided services which affect flight critical systems and take appropriate actions if real-time performance could lead to the loss of control of the operation. | Same as Medium. In addition:   * The evidence of the externally provided service performance is achieved through demonstrations. * A competent third party validates the claimed level of integrity. |
| *Comments* | *N/A* | *N/A* | *N/A* |

# *Human Error*

## OSO #16 - Multi crew coordination

* *Contributing JARUS WG(s): WG1 and WG2*

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| --- | --- | --- | --- | --- |
| **HUMAN ERROR** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #16 Multi crew coordination** | Criterion #1  (Procedures) | Procedure(s) to ensure a coordination between the crew members with robust and effective communication channels is (are) available and covers at minimum:   * assignment of tasks to the crew, * establishment of a step-by-step communication. | | |
| *Comments* | *The modulation of the level of robustness of this criterion is achieved through the level of assurance as per Table below.* | | |
| Criterion #2  (Training) | Remote Crew training covers multi crew coordination | Same as Low. In addition, the Remote Crew1 receives a Crew Resource Management (CRM)2 training. | Same as Medium. |
| *Comments* | *N/A* | *1 In the context of SORA, the term “Remote crew” refers to any person involved in the mission.*  *2 CRM training focuses on the effective use of all remote crew to assure a safe and efficient operation, reducing error, avoiding stress and increasing efficiency.* | *N/A* |
| Criterion #3  (Communication devices) | N/A | Communication devices are in compliance with recognized adequate standards | Communication devices are redundant and in compliance with recognized adequate standards |
| *Comments* | *N/A* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* |

| **HUMAN ERROR** | | **LEVEL of ASSURANCE** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #16 Multi crew coordination** | Criterion #1  (Procedures) | * Procedures are not required to be validated against a recognized standard. * The adequacy of the procedures and checklists is declarative. | * Procedures are validated against recognized standards. * The adequacy of the procedures is proved through:   + Dedicated flight tests, or   Simulation, provided that the representativeness of the simulation means is proven for the intended purpose with positive results. | Same as Medium. In addition:   * Any flight test performed to validate the procedures cover the complete flight envelope or be proven to be conservative. * The procedures, flight tests and simulations are validated by a competent third party. |
| *Comments* | *N/A* | *N/A* | *N/A* |
| Criterion #2  (Training) | Training is self-declared (with evidence available) | * Training syllabus is available * Competency-based theoretical and practical training organised by the operator | A competent third party:   * Validates the training syllabus. * Verifies the remote crew competencies. |
| *Comments* | *N/A* | *N/A* | *N/A* |
| Criterion #3  (Communication devices) | The level of assurance associated to this criterion needs to be assessed considering a technical OSO nature (refer to section 9) | | |
| *Comments* | *N/A* | *N/A* | *N/A* |

## OSO #17 - Remote crew is fit to operate

* *Contributing JARUS WG(s): WG1*

1. In the following, the expression “fit to operate” needs to be understood as physically and mentally fit to perform duties and discharge responsibilities safely.
2. Fatigue and stress are contributory factors to human error. Therefore, in order to ensure that vigilance is maintained at a satisfactory level in terms of safety, consideration must be given to the following:
   * Remote Crew duty times;
   * Regular breaks;
   * Rest periods;
   * Handover/Take Over procedures.

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| **HUMAN ERROR** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #17**  **Remote crew is fit to operate** | Criteria | The applicant has a policy defining how the remote crew can declare themselves fit to operate before conducting any operation. | Same as Low. In addition, resting times for the remote crew are defined by the applicant and adequate for the operation. | Same as Medium. In addition, a fatigue risk management program is available. |
| *Comments* | *N/A* | *N/A* | *N/A* |

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| --- | --- | --- | --- | --- |
| **HUMAN ERROR** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #17**  **Remote crew is fit to operate** | Criteria | The remote crew declare they are fit to operate before conducting any operation based on the policy defined by the applicant. | Same as Low. In addition:   * Resting times policy is documented. * Remote crew duty cycles are logged and covered at minimum:   + when a remote crew member’s duty day commences,   + when the crew member is free from duties,   + resting times within the duty cycle. | Same as Medium. In addition:   * A competent third party checks that the remote crew is medically fit. * A competent third party validates the fatigue risk management program. |
| *Comments* | *N/A* | *N/A* | *N/A* |

## OSO #18 - Automatic protection of the flight envelope from human errors

* *Contributing JARUS WG(s): WG3*

1. Unmanned Aircraft (UA) are designed with a flight envelope that describes its safe performance limits in regard to minimum and maximum operating speeds, and operating structural strength.
2. Automatic protection of the flight envelop intend to prevent the remote pilot from operating the UA outside its flight envelope. If the applicant demonstrates that the remote-pilot is not in the loop, this OSO is not applicable.
3. UAS implementing such automatic protection function will ensure the UA is operated within an acceptable flight envelope margin even in the case of incorrect remote-pilot control input (human error).
4. UAS without automatic protection function are susceptible to incorrect remote-pilot control input (human error) which can result in loss of the UA if the designed performance limits of the aircraft are exceeded.

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| **HUMAN ERROR** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #18**  **Automatic protection of critical flight functions** | Criteria | The UAS flight control system incorporates automatic protection of the flight envelope to prevent the remote pilot from making any single input under normal operating conditions that would cause the UA to exceed its flight envelope or prevent it from recovering in a timely fashion. | The UAS flight control system incorporates automatic protection of the flight envelope to ensure the UA remains within or timely recovers to the designed operational flight envelope following remote pilot error(s). | |
| *Comments* | *The modulation of the level of robustness of this OSO is achieved through the level of assurance (see table below).* | | |

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| --- | --- | --- | --- | --- |
| **HUMAN ERROR** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #18**  **Automatic protection of critical flight functions** | Criteria | The automatic protection of the flight envelope has been developed in-house or out of the box (e.g. using Component Off The Shelf elements), without following specific standards. | The automatic protection of the flight envelope has been developed following recognized adequate standards. | The automatic protection of the flight envelope has been developed following recognized adequate standards and checked by a competent third party. |
| *Comments* | *N/A* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* |

## OSO #19 - Safe recovery from Human Error

* *Contributing JARUS WG(s): WG3*

1. This OSO is intended to cover the risk of human errors from any person involved with the mission, which may affect the safety of the operation if not prevented or detected and recovered in a timely fashion.
   1. An example could be a human error leading to incorrect loading of the payload, with the risk to fall off the UA during the operation.
   2. Another example could be a human error not to extend the antenna mast, reducing the C2 link coverage.

Note: the flight envelope protection is excluded from this OSO since specifically covered by OSO #18.

1. This OSO covers:
   1. Procedures and checklists,
   2. Training, and
   3. UAS design (i.e. any human error detection and /or recovery system).

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| --- | --- | --- | --- | --- |
| **HUMAN ERROR** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #19**  **Safe recovery from Human Error** | Criterion #1  (Procedures and checklists) | Procedures and checklists mitigate the risk of potential human errors from any person involved with the mission.  Procedures provide at a minimum:   * a clear distribution and assignment of tasks, * an internal checklist to check that staff is properly performing assigned task adequately. | | |
| *Comments* | *N/A* | *N/A* | *N/A* |
| Criterion #2  (Training) | * The Remote Crew1 is trained to procedures and checklists. * The Remote Crew1 receives a Crew Resource Management (CRM)2 training. | | |
| *Comments* | *1 In the context of SORA, the term “Remote crew” refers to any person involved in the mission.*  *2 CRM training focuses on the effective use of all remote crew to assure a safe and efficient operation, reducing error, avoiding stress and increasing efficiency.*  *The modulation of the level of robustness of this specific criterion is achieved through the level of assurance (see table below)* | | |
| Criterion #3  (UAS design) | Systems detecting and/or recovering from human errors are developed to industry best practices. | Systems detecting and/or recovering from human errors are developed to recognized adequate standards. | Same as medium. |
| *Comments* | *N/A* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* | *N/A* |

| **HUMAN ERROR** | | **LEVEL of ASSURANCE** | | |
| --- | --- | --- | --- | --- |
| **Low** | **Medium** | **High** |
| **OSO #19**  **Safe recovery from Human Error** | Criterion #1  (Procedures and checklists) | * Procedures and checklists are not required to be validated against a recognized standard. * The adequacy of the procedures and checklists is declarative. | * Procedures and checklists are validated against recognized standards. * The adequacy of the procedures and checklists is proved through:   + Dedicated flight tests, or   + Simulation, provided that the representativeness of the simulation means is proven for the intended purpose with positive results. | Same as Medium. In addition:   * Any flight test performed to validate the procedures and checklists cover the complete flight envelope or be proven to be conservative. * A competent third party validates the procedures, checklists, flight tests and simulations. |
| *Comments* | *N/A* | *N/A* | *N/A* |
| Criterion #2  (Training) | Refer to the criteria defined for level of assurance of the generic remote crew training OSO (i.e. OSO #09, OSO #15 and OSO #22) corresponding to the SAIL of the operation | | |
| *Comments* | *N/A* | *N/A* | *N/A* |
| Criterion #3  (UAS design) | The level of assurance associated to this criterion needs to be assessed considering a technical OSO nature (refer to section 9) | | |
| *Comments* | *N/A* | *N/A* | *N/A* |

## OSO #20 - A Human Factors evaluation has been performed and the HMI found appropriate for the mission

* *Contributing JARUS WG(s): WG3*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **HUMAN ERROR** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #20**  **A Human Factors evaluation has been performed and the HMI found appropriate for the mission** | Criteria | The UAS information and control interfaces are clearly and succinctly presented and do not confuse, cause unreasonable fatigue, or contribute to remote crew error that could adversely affect the safety of the operation. | | |
| *Comments* | If an electronic means is used to support potential Visual Observers in their role to maintain awareness of the position of the unmanned aircraft, its HMI:   * is sufficient to allow the Visual Observers to determine the position of the UA during operation; * does not degrade the Visual Observer’s ability to: * scan the airspace visually where the unmanned aircraft is operating for any potential collision hazard; and * maintain effective communication with the remote pilot at all times. | | |

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| --- | --- | --- | --- | --- |
| **HUMAN ERROR** | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **OSO #20**  **A Human Factors evaluation has been performed and the HMI found appropriate for the mission** | Criteria | The applicant conducts an evaluation of the UAS considering and addressing human factors to determine the HMI is appropriate for the mission. The Human-Machine Interface evaluation is based on Engineering Evaluations or Analyses. | Same as Low. In addition, the Human-Machine Interface evaluation is based on simulations for which representativeness of targeted simulation environment is proven. | Same as Medium. In addition, a competent third party witnesses the Human-Machine Interface evaluation. |
| *Comments* | *N/A* | *N/A* | *N/A* |

# *Adverse Operating Conditions*

## OSO #23 - Environmental conditions for safe operations defined, measurable and adhered to

* *Contributing JARUS WG(s): WG1, WG2, WG3*

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| --- | --- | --- | --- | --- |
| **ADVERSE OPERATING CONDITIONS** | | **LEVEL of INTEGRITY** | | |
| **Low** | **Medium** | **High** |
| **OSO #23**  **Environmental conditions for safe operations defined, measurable and adhered to** | Criterion #1  (Definition) | Environmental conditions for safe operations are defined and reflected in the flight manual or equivalent document | | |
| *Comments* | *The modulation of the level of robustness is achieved through the level of assurance (see table below)* | | |
| Criterion #2  (Procedures) | Procedures to evaluate environmental conditions before and during the mission (i.e. real-time evaluation) are available and include assessment of meteorological conditions (METAR, TAFOR, etc.) with a simple record system. | | |
| *Comments* | *The modulation of the level of robustness is achieved through the level of assurance (see table below)* | | |
| Criterion #3  (Training) | Training covers assessment of meteorological conditions | | |
| *Comments* | *The modulation of the level of robustness is achieved through the level of assurance (see table below)* | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ADVERSE OPERATING CONDITIONS** | | **LEVEL of ASSURANCE** | | | | |
| **Low** | | **Medium** | | **High** |
| **OSO #23**  **Environmental conditions for safe operations defined, measurable and adhered to** | Criterion #1  (Definition) | The level of assurance of this element of the OSO needs to be assessed considering the criteria provided in section 9. | | | | |
| *Comments* | *N/A* | | | | |
| Criterion #2  (Procedures) | * Procedures are not required to be validated against a recognized standard. * The adequacy of the procedures and checklists is declarative. | * Procedures are validated against recognized standards. * The adequacy of the procedures is proved through:   + Dedicated flight tests, or   + Simulation, provided that the representativeness of the simulation means is proven for the intended purpose with positive results. | | Same as Medium. In addition:   * Any flight test performed to validate the procedures cover the complete flight envelope or be proven to be conservative. * The procedures, flight tests and simulations are validated by a competent third party. | |
| *Comments* | *N/A* | *N/A* | | *N/A* | |
| Criterion #3  (Training) | Training is self-declared (with evidence available) | * Training syllabus is available * Competency-based theoretical and practical training organised by the operator | | A competent third party:   * Validates the training syllabus. * Verifies the remote crew competencies. | |
| *Comments* | *N/A* | *N/A* | | *N/A* | |

## OSO #24 - UAS designed and qualified for adverse environmental conditions (e.g. adequate sensors, DO-160 qualification)

* *Contributing JARUS WG(s): WG3*

1. In order to correctly assess the integrity of this OSO, the applicant should check the following aspects:
   * Check which credit can be taken from the equipment environmental qualification tests / declarations:
     1. *Is the equipment having an (E)TSO and is the Declaration of Design and Performance (DDP) available to the applicant (the DDP should state the environmental qualification levels to which the equipment was tested)?*
     2. *Were the environmental qualification tests performed following a recognized adequate standard (e.g. DO-160)?*
     3. *If the tests were not performed following a recognized standard, were the test performed by an organisation/entity being qualified or having experience in performing like DO-160 tests?*
   * Check the suitability of the boundaries of the equipment environmental qualification tests /declarations by determining if they are sufficient for the intended operation of the aircraft and ground system equipment considering the environmental conditions that the UAS is intended/expected to encounter when it is operated.

Note: environmental conditions that the UAS is intended/expected to encounter when it is operated are supposed to be already defined under “Environmental conditions for safe operations defined, measurable and adhered to”

* + Check the availability of in-service experience or generic (or other application) test results, which could be taken credit of to determine the tolerance of the equipment to the intended/expected UAS environment conditions.
  + Define any limitations, which would make the use of equipment suitable for the UAS operation.

1. In the case where a UAS would have part of the equipment having an environmental qualification, a part having a demonstration by similarity, a part of equipment not having any qualification at all, the lowest integrity level should be considered.

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| --- | --- | --- | --- | --- |
| **ADVERSE OPERATING CONDITIONS** | | **LEVEL of INTEGRITY** | | |
| **N/A** | **Medium** | **High** |
| **OSO #24**  **UAS designed and qualified for adverse environmental conditions** | Criteria | N/A | The UAS is designed to limit the effect of environmental conditions. | The UAS is designed considering adequate environmental standards. |
| *Comments* | *N/A* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* | *A list of adequate industry standards (existing or to be established) will be identified by Eurocae WG105 by September 2018.* |

| **ADVERSE OPERATING CONDITIONS** | | **LEVEL of ASSURANCE** | | |
| --- | --- | --- | --- | --- |
| **N/A** | **Medium** | **High** |
| **OSO #24**  **UAS designed and qualified for adverse environmental conditions** | Criteria | N/A | The level of assurance of this OSO needs to be assessed considering the criteria provided in section 9. | |
| *Comments* | *N/A* | *N/A* | |

# *Assurance levels definition for technical OSO*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | **LEVEL of ASSURANCE** | | |
| **Low** | **Medium** | **High** |
| **TECHNICAL OSO** | Criteria | The applicant declares that the required level of integrity has been achieved1. | The applicant has supporting evidences that the required level of integrity has been achieved. This is typically done by means of testing, analysis, simulation1, inspection, design review or through operational experience. | A competent third party validates the claimed level of integrity. |
| *Comments* | *1 Supporting evidences may or may not be available* | *1* When simulation is used, representativeness of targeted environment needs to be justified*.* | *N/A* |