

# **JARUS** guidelines on SORA

# Annex E

# Integrity and assurance levels for the Operation Safety Objectives (OSO)

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# 1. How to use SORA Annex E

The following table provides the basic principles to consider when using SORA Annex E.

	Principle description	Additional information
#1	Annex E provides assessment criteria for the integrity (i.e. safety gain) and assurance (i.e. method of proof) of Operation Safety Objectives (OSOs) proposed by an applicant.	The identification of Operation Safety Objectives for a given operation, is the responsibility of the applicant.
#2	Annex E does not cover the Level of Involvement (LoI) of the Competent Authority. LoI is based on the Competent Authority assessment of the applicant's ability to perform the given operation.	Some JARUS groups (e.g. WG-7) might provide criteria for level of involvement for use by the Competent Authorities.
#3	To achieve a given level of integrity/assurance, when more than one criterion exists for that level of integrity/assurance, all applicable criteria need to be met.	
#4	"Optional" cases defined in SORA Main Body Table 8 do not need to be defined in terms of integrity and assurance levels in Annex E.	All robustness levels are acceptable for Operation Safety Objectives for which an "optional" level of robustness is defined in Table 6 "Recommended operation safety objectives (OSO)" of the SORA Main Body.
#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 intentionally uses non-prescriptive terms (e.g. suitable, reasonably practicable) to provide flexibility to both the applicant and the Competent Authorities. This does not constrain the applicant in proposing mitigations, nor the Competent Authority in evaluating what is needed on a case by case basis.	
#7	This annex in its entirety also applies to single-person organizations.	

# 2. Technical issue with the UAS

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

TECHNICAL ISSUE WITH THE		LEVEL of INTEGRITY			
L	JAS	Low	Medium	High	
OSO #01 Ensure the operator is competent and/or proven	Criteria	The applicant is knowledgeable of the UAS being used and as a minimum has the following relevant operational procedures: checklists, maintenance, training, responsibilities, and associated duties.	Same as Low. In addition, the applicant has an organization appropriate <sup>7</sup> for the intended operation. Also the applicant has a method to identify, assess, and mitigate risks associated with flight operations. These should be consistent with the nature and extent of the operations specified.	Same as Medium.	
	Comments	N/A	<sup>1</sup> For the purpose of this assessment appropriate should be interpreted as commensurate/proportionate with the size of the organization and the complexity of the operation.	N/A	

TECHNICAL ISSUE WITH THE		LEVEL of ASSURANCE			
U	AS	Low	Medium	High	
OSO #01 Ensure the operator is competent and/or proven	Criteria	The elements delineated in the level of integrity are addressed in the ConOps.	Prior to the first operation, a competent third party performs an audit of the organization	The applicant holds an Organizational Operating Certificate or has a recognized flight test organization. In addition, a competent third party recurrently verifies the operator competences.	
proven	Comments	N/A	N/A	N/A	

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

TECHNICAL IS	SUE WITH THE		LEVEL of INTEGRITY	
U	AS	Low	Medium	High
OSO #02 UAS manufactured by competent and/or proven entity	Criteria	<ul> <li>As a minimum, manufacturing procedures cover:</li> <li>specification of materials</li> <li>suitability and durability of materials used,</li> <li>processes necessary to allow for repeatability in manufacturing and conformity within acceptable tolerances.</li> </ul>	<ul> <li>Same as Low. In addition, manufacturing procedures also cover:</li> <li>configuration control,</li> <li>verification of incoming products, parts, materials, and equipment,</li> <li>identification and traceability,</li> <li>in-process and final inspections &amp; testing,</li> <li>control and calibration of tools,</li> <li>handling and storage,</li> <li>non-conforming item control.</li> </ul>	Same as Medium. In addition, the manufacturing procedures cover at least: manufacturing processes, personnel competence and qualification, supplier control.
	Comments	N/A	N/A	N/A

TECHNICAL IS	SUE WITH THE	LEVEL of ASSURANCE			
U.	AS	Low	Medium	High	
OSO #02 UAS manufactured by	Criteria	The declared manufacturing procedures are developed to a standard considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority.	Same as Low. In addition, evidence is available that the UAS has been manufactured in conformance to its design.	<ul> <li>Same as Medium. In addition:</li> <li>manufacturing procedures,</li> <li>conformity of the UAS to its design and specification</li> </ul> are recurrently verified through process or product audit by a competent third party(ies).	
by competent and/or proven entity	Comments	National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	N/A	N/A	

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

TECHNICAL I	SSUE WITH THE	LEVEL of INTEGRITY		
L	JAS	Low	Medium	High
OSO #03 UAS maintained by competent and/or proven entity (e.g. industry standards)	Criteria	<ul> <li>The UAS <u>maintenance instructions</u> are defined and when applicable cover the UAS designer instructions and requirements.</li> <li>The maintenance staff is competent and has received an authorisation to carry out UAS maintenance.</li> <li>The maintenance staff use the UAS maintenance instructions while performing maintenance.</li> </ul>	<ul> <li>Same as Low. In addition:</li> <li>Scheduled maintenance of each UAS is organised and in accordance with a <u>Maintenance</u> <u>Programme.</u></li> <li>Upon completion, the maintenance log system is used to record all maintenance conducted on the UAS including releases. A maintenance release can only be accomplished by a staff member who has received a maintenance release authorisation for that particular UAS model/family.</li> </ul>	Same as Medium. In addition, the maintenance staff works in accordance with a <u>maintenance procedure manual</u> that provides information and procedures relevant to the maintenance facility, records, maintenance instructions, release, tools, material, components, defect deferral
	Comments	N/A	N/A	N/A

TECHNICAL I	SSUE WITH THE		LEVEL of ASSURANCE	
L	JAS	Low	Medium	High
	Criterion #1 (Procedure)	<ul> <li>The maintenance instructions are documented.</li> <li>The maintenance conducted on the UAS is recorded in a maintenance log system <sup>1/2</sup>.</li> <li>A list of maintenance staff authorised to carry out maintenance is established and kept up to date.</li> </ul>	<ul> <li>Same as Low. In addition:</li> <li>The Maintenance Programme is developed in accordance with standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority<sup>3</sup>.</li> <li>A list of maintenance staff with maintenance release authorisation is established and kept up to date.</li> </ul>	Same as Medium. In addition, the maintenance programme and the maintenance procedures manual are validated by a competent third party.
OSO #03 UAS maintained by competent and/or proven	Comments	<ol> <li><sup>1</sup> Objective is to record all the maintenance performed on the aircraft, and why it is performed (defects or malfunctions rectification, modification, scheduled maintenance etc.)</li> <li><sup>2</sup> The maintenance log may be requested for inspection/audit by the approving authority or an authorized representative.</li> </ol>	<sup>3</sup> National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	N/A
entity (e.g. industry standards)	Criterion #2 (Training)	A record of all relevant qualifications, experience and/or trainings completed by the maintenance staff is established and kept up to date.	<ul> <li>Same as Low. In addition:</li> <li><u>Initial</u> training syllabus and training standard including theoretical/practical elements, duration, etc. is defined and commensurate with the authorisation held by the maintenance staff.</li> <li>For staff holding a maintenance release authorisation, the <u>initial</u> training is specific to that particular UAS model/family.</li> <li>All maintenance staff have undergone <u>initial</u> training.</li> </ul>	<ul> <li>Same as Medium. In addition:</li> <li>A programme for <u>recurrent</u> training of staff holding a maintenance release authorisation is established; and</li> <li>This programme is validated by a competent third party.</li> </ul>
	Comments	N/A	N/A	N/A

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

TECHNICAL ISSUE WITH THE		LEVEL of INTEGRITY			
ι	JAS	Low	Medium	High	
OSO #04 UAS developed to authority recognized design standards	Criteria	The UAS is designed to standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority. The standards and/or the means of compliance should be applicable to a <u>Low</u> Level of Integrity and the intended operation.	The UAS is designed to standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority. The standards and/or the means of compliance should be applicable to a <u>Medium</u> Level of Integrity and the intended operation.	The UAS is designed to standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority. The standards and/or the means of compliance should be applicable to a <u>High</u> Level of Integrity and the intended operation.	
Stanuarus	Comments		v define the standards and/or the means of later point in time with a list of adequate st		

TECHNICAL ISSUE WITH THE		LEVEL of ASSURANCE		
U/	AS	Low	Medium	High
OSO #04 UAS	Criteria	Consider the criteria defined in section 9		
developed to authority recognized design standards	Comments	N/A	N/A	N/A

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

- (a) This OSO complements:
- The safety requirements for containment defined in the main Body
- OSO #10 and OSO #12, which is only addressing the risk of a fatality while operating over populous areas or gatherings of people.

<b>TECHNICAL</b>	SSUE WITH THE		LEVEL of INTEGRITY	
	JAS	Low	Medium	High
OSO #05 UAS is designed considering system safety and reliability	Criteria	The equipment, systems, and installations are designed to minimize hazards <sup>1</sup> in the event of a probable <sup>2</sup> malfunction or failure of the UAS.	Same as Low. In addition, the strategy for detection, alerting and management of any malfunction, failure or combination thereof, which would lead to a hazard is available.	<ul> <li>Same as Medium. In addition:</li> <li>Major Failure Conditions are not more frequent than Remote<sup>3</sup>;</li> <li>Hazardous Failure Conditions are not more frequent than Extremely Remote<sup>3</sup>;</li> <li>Catastrophic Failure Conditions are not more frequent than Extremely Improbable<sup>3</sup>;</li> <li>Software (SW) and Airborne Electronic Hardware (AEH) whose development error(s) may cause or contribute to hazardous or catastrophic failure conditions are developed to an industry standard or a methodology considered adequate by the competent authority and/or in accordance with means of compliance acceptable to that authority<sup>4</sup>.</li> </ul>
	Comments	<ul> <li><sup>1</sup> For the purpose of this assessment, the term "hazard" should be interpreted as a failure condition that relates to major, hazardous, or catastrophic.</li> <li><sup>2</sup> For the purpose of this assessment, the term "probable" should be interpreted in a qualitative way as, "Anticipated to occur one or more times during the entire system/operational life of an UAS".</li> </ul>	N/A	<ul> <li><sup>3</sup> Safety objectives may be derived from JARUS AMC RPAS.1309 Issue 2 Table 3 depending on the UAS class or an equivalent risk-based methodology acceptable to the competent authority.</li> <li><sup>4</sup> Development Assurance Levels (DALs) for SW/AEH may be derived from JARUS AMC RPAS.1309 Issue 2 Table 3 depending on the UAS class or an equivalent risk-based methodology acceptable to the competent authority.</li> </ul>

TECHNICAL ISSUE WITH THE			LEVEL of ASSURANCE	LEVEL of ASSURANCE		
ι	JAS	Low	Medium	High		
OSO #05 UAS is designed considering system	Criteria	A Functional Hazard Assessment <sup>1</sup> and a design and installation appraisal that shows hazards are minimized are available.	<ul> <li>Same as Low. In addition:</li> <li>Safety analyses are conducted in line with standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority.</li> <li>A strategy for detection of single failures of concern includes pre-flight checks.</li> </ul>	Same as Medium. In addition, safety analyses and development assurance activities are validated by a competent third party.		
safety and reliability	Comments	<sup>1</sup> Severity of failures conditions (No Safety Effect, Minor, Major, Hazardous and Catastrophic) should be determined according to the definitions provided in JARUS AMC RPAS.1309 Issue 2.	N/A	N/A		

#### OSO #06 - C3 link characteristics (e.g. performance, spectrum use) are appropriate for the operation

- (a) 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.
- (b) To correctly assess the integrity of this OSO, the applicant should identify:
  - 1) The C3 links performance requirements necessary for the intended operation.
  - 2) All C3 links, together with their actual performance and Radio Frequency (RF) spectrum usage.
    - <u>Note</u>: The specification of performance and RF spectrum for a C2 Link is typically documented by the UAS designer in the UAS manual.

<u>Note</u>: Main parameters associated with C2 link performance (RLP) and the performance parameters for other communication links (e.g. RCP for communication with ATC) include, but are not limited to the following:

- $\circ$  Transaction expiration time
- Availability
- $\circ$  Continuity
- o Integrity

Refer to ICAO references for definitions.

- 3) The RF spectrum usage requirements for the intended operation (including the need for authorization if required). <u>Note</u>: 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. However, the applicant should check the local requirements and request authorization when needed since there may be national differences and specific allocations (e.g. national sub-division of ITU allocations). Some aeronautical bands (e.g. AM(R)S, AMS(R)S 5030-5091MHz) were allocated for potential use in UAS operations under ICAO scope for UAS operations classified as cat. C ("certified"), but their use may be authorized for operations under the specific category. It is expected that the use of other licensed bands (e.g. those allocated to mobile networks) may also be authorized under the specific category. Some un-licensed bands (e.g. ISM (Industrial, Scientific, Medical) or SRD (Short Range Devices)) may also be acceptable under the specific category, for instance for operations with lower integrity requirements.
- 4) Environmental conditions that might affect the C3 links performance.

TECHNICAL ISSUE WITH THE			LEVEL of INTEGRITY	
U	AS	Low	Medium	High
	Criteria	<ul> <li>The applicant determines that performance, RF spectrum usage<sup>1</sup> and environmental conditions for C3 links are adequate to safely conduct the intended operation.</li> <li>The UAS remote pilot has the means to continuously monitor the C3 performance and ensures the performance continues to meet the operational requirements<sup>2</sup>.</li> </ul>	Same as Low <sup>3</sup> .	Same as Low. In addition, the use of licensed <sup>4</sup> frequency bands for C2 Link is required.
OSO #06 C3 link characteristics (e.g. performance, spectrum use) are appropriate for the operation	Comments	<ul> <li><sup>1</sup> For a low level of integrity, unlicensed frequency bands might be acceptable under certain conditions, e.g.:</li> <li>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), by showing the UAS equipment is compliant with these requirements (e.g. FCC marking), and</li> <li>the use of mechanisms to protect against interference (e.g. FHSS, frequency deconfliction by procedure).</li> <li><sup>2</sup> The remote pilot has continual and timely access to the relevant C3 information that could affect the safety of flight. For operations requesting only a low level of integrity for this OSO, this could be achieved by monitoring the C2 link signal strength and receiving an alert from the UAS HMI if the signal becomes too low.</li> </ul>	<sup>3</sup> Depending on the operation, the use of licensed frequency bands might be necessary. In some cases, the use of non-aeronautical bands (e.g. licensed bands for cellular network) may be acceptable.	<sup>4</sup> This ensures a minimum level of performance and is not limited to aeronautical licensed frequency bands (e.g. licensed bands for cellular network). Nevertheless some 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 authorization.

TECHNICAL ISSUE WITH THE		LEVEL of ASSURANCE		
UAS		Low	Medium	High
OSO #06 C3 link characteristics (e.g. performance,	Criteria	Consider the assurance criteria defined in section 9 (low level of assurance)	Demonstration of the C3 link performance is in accordance with standards considered adequate by the competent authority and/or in accordance with means of compliance acceptable to that authority.	Same as Medium. In addition, evidence is validated by a competent third party.
spectrum use) are appropriate for the operation	Comments	N/A	National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	N/A

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

(a) The intent of this OSO assure the UAS used for the operation conforms to the UAS data used to support the approval/authorization of the operation.

TECHNICAL ISSUE WITH THE		LEVEL of INTEGRITY			
ι	JAS	Low	Medium	High	
OSO #07 Inspection of the UAS (product inspection)	Criteria	The remote crew ensures the UAS is in a condition for safe operation and conforms to the approved concept of operation			
to ensure consistency to the ConOps	Comments	<sup>1</sup> The distinction between a low, a mediur assurance (see table below).	n and a high level of robustness for this cr	iterion is achieved through the level of	

TECHNICAL ISSUE WITH THE UAS			LEVEL of ASSURANCE	
		Low	Medium	High
OSO #07	Criterion #1 (Procedures)	Product inspection is documented and accounts for the manufacturer's recommendations if available.	Same as Low. In addition, the product inspection is documented using checklists.	Same as Medium. In addition, the product inspection is validated by a competent third party.
Inspection of the UAS	Comments	N/A	N/A	N/A
(product inspection) to ensure consistency to the ConOps	Criterion #2 (Training)	The remote crew's is trained to perform the product inspection, and that training is self-declared (with evidence available).	<ul> <li>A training syllabus including a product inspection procedure is available.</li> <li>The operator provides competency-based, theoretical and practical training.</li> </ul>	<ul> <li>A competent third party:</li> <li>Validates the training syllabus.</li> <li>Verifies the remote crew competencies.</li> </ul>
	Comments	N/A	N/A	N/A

#### 3. OSOs related to 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)

OPERATIONAL PROCEDURES			LEVEL of INTEGRITY		
		Low	Medium	High	
	Criterion #1 (Procedure definition)	<ul> <li>Operational procedures<sup>1</sup> appropriate for the proposed operation are defined and as a minimum cover the following elements:         <ul> <li>Flight planning,</li> <li>Pre and post-flight inspections,</li> <li>Procedures to evaluate environmental conditions before and during the mission (i.e. real-time evaluation),</li> <li>Procedures to cope with unintended adverse operating conditions (e.g. when ice is encountered during operation not approved for icing conditions)</li> <li>Normal procedures,</li> <li>Contingency procedures (to cope with abnormal situations),</li> <li>Emergency procedures (to cope with emergency situations), and</li> <li>Occurrence reporting procedures.</li> </ul> </li> <li>Normal, Contingency and Emergency procedures are compiled in an Operation Manual.</li> </ul>			
OSO #08, OSO #11, OSO #14 and OSO #21	Comments	<ul> <li><sup>1</sup>Operational procedures cover the deterioration<sup>3</sup> of the UAS itself and any external system supporting UAS operation.</li> <li><sup>2</sup> In the scope of this assessment, external systems supporting UAS operation are defined as systems not already part of the UAS but used to:</li> <li>launch / take-off the UAS,</li> <li>make pre-flight checks,</li> <li>keep the UA within its operational volume (e.g. GNSS, Satellite Systems, Air Traffic Management, UTM).</li> <li>External systems activated/used after the loss of control of the operation are <u>excluded</u> from this definition.</li> <li><sup>3</sup>To properly address deterioration of external systems required for the operation, it is recommended to: <ul> <li>identify these "external systems",</li> <li>identify these "external systems",</li> <li>identify the external systems deterioration modes (e.g. complete loss of GNSS, drift of the GNSS, latency issues,) which would lead to a loss of control of the operation,</li> <li>describe the means to detect these deterioration modes of the external systems/facilities,</li> <li>describe procedure(s) used when deterioration is detected (e.g. activation of the Emergency Recovery Capability switch to a manual control).</li> </ul> </li> </ul>			
	Criterion #2 (Procedure complexity)	Operational procedures are complex and may potentially jeopardize the crew ability to respond by raising the remote crew's workload and/or the interactions with other entities (e.g. ATM).	Contingency/emergency procedures require manual control by the remote pilot <sup>2</sup> when the UAS is usually automatically controlled.	Operational procedures are simple.	
	Comments	N/A	<sup>2</sup> This is still under discussion since not all UAS have a mode where the pilot could directly control the surfaces; moreover, some people claim it requires significant skill not to make things worse.	N/A	
	Criterion #3 (Consideration of Potential Human Error)	<ul> <li>At a minimum, operational procedures provide:</li> <li>a clear distribution and assignment of tasks</li> <li>an internal checklist to ensure staff are adequately performing assigned tasks.</li> </ul>	Operational procedures take human error into consideration.	Same as Medium. In addition, the Remote Crew <sup>3</sup> receives Crew Resource Management (CRM) <sup>4</sup> training.	
	Comments	N/A	N/A	<ul> <li><sup>3</sup> In the context of SORA, the term "Remote crew" refers to any person involved in the mission.</li> <li><sup>4</sup> 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.</li> </ul>	

			LEVEL of ASSURANCE	
OPERATIONAL PROCEDURES		Low	Medium	High
OSO #08, OSO #11, OSO #14 and OSO #21	Criteria	<ul> <li>Operational procedures do not require validation against either a standard or a means of compliance considered adequate by the competent authority.</li> <li>The adequacy of the operational procedures is declared, except for Emergency Procedures, which are tested.</li> </ul>	<ul> <li>Operational procedures are validated against standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority<sup>1</sup>.</li> <li>Adequacy of the Contingency and Emergency procedures is proven through:         <ul> <li>Dedicated flight tests, or</li> <li>Simulation provided the simulation is proven valid for the intended purpose with positive results.</li> </ul> </li> </ul>	<ul> <li>Same as Medium. In addition:</li> <li>Flight tests performed to validate the procedures and checklists cover the complete flight envelope or are proven to be conservative.</li> <li>The procedures, checklists, flight tests and simulations are validated by a competent third party.</li> </ul>
	Comments	N/A	<sup>1</sup> National Aviation Authorities (NAAs) m means of compliance they consider ade updated at a later point in time with a list feedback provided by the NAAs.	quate. The SORA Annex E will be

#### 4. OSOs related to 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

(a) The applicant needs to propose competency-based, theoretical and practical training:

- appropriate for the operation to be approved, and
- including proficiency requirements and training recurrences.
- (b) 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 ...).

REMOTI	E CREW		LEVEL of INTEGRITY	
COMPETENCIES		Low	Medium	High
OSO #09, OSO #15 and OSO #22	Criteria	The competency-based, theoretical and p a) UAS regulation b) UAS airspace operating print c) Airmanship and aviation safe d) Human performance limitation e) Meteorology f) Navigation/Charts g) UA knowledge h) Operating procedures and is adequate for the operation. <sup>1/2</sup>	ciples	
	Comments		or the different subjects listed above will be n and a high level of robustness for this cr	

		LEVEL of ASSURANCE		
REMOTE CREV	COMPETENCIES	Low	Medium	High
OSO #09, OSO #15 and OSO #22	Criteria	Training is self-declared (with evidence available).	<ul> <li>Training syllabus is available.</li> <li>The operator provides competency-based, theoretical and practical training.</li> </ul>	<ul> <li>A competent third party:</li> <li>Validates the training syllabus.</li> <li>Verifies the remote crew competencies.</li> </ul>
	Comments	N/A	N/A	N/A

#### 5. OSOs related to 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

- (a) The objective of OSO#10 and OSO#12 is to complement the technical containment safety requirements by addressing the risk of a fatality while operating over populous areas or gatherings of people.
- (b) In the scope of this assessment, external systems supporting UAS 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 operational 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.

		LEVEL of INTEGRITY		
		Low	Medium	High
OSO #10 & OSO #12	Criteria	When operating over populous areas or gatherings of people, it can be reasonably expected that a fatality will not occur from any <u>probable<sup>1</sup> failure<sup>2</sup></u> of the UAS or any external system supporting the operation.	<ul> <li>When operating over populous areas or gatherings of people:</li> <li>It can be reasonably expected that a fatality will not occur from any <u>single failure</u><sup>3</sup> of the UAS or any external system supporting the operation.</li> <li>Software (SW) and Airborne Electronic Hardware (AEH) whose development error(s) could directly lead to a failure affecting the operation in such a way that it can be reasonably expected that a fatality will occur are developed to a standard considered adequate by the competent authority and/or in accordance with means of compliance acceptable to that authority<sup>4</sup>.</li> </ul>	Same as Medium
	Comments	<ul> <li><sup>1</sup> For the purpose of this assessment, the term "probable" should be interpreted in a qualitative way as, "Anticipated to occur one or more times during the entire system/operational life of an UAS".</li> <li><sup>2</sup> 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.</li> </ul>	<sup>3</sup> 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 a standard considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority <sup>4</sup> National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	

				LEVEL of ASSURANCE	
			Low	Medium	High
	OSO #10 & OSO #12	Criteria	<ul> <li>A design and installation appraisal is available. In particular, this appraisal shows that:</li> <li>the design and installation features (independence, separation and redundancy) satisfy the low integrity criterion;</li> <li>particular risks relevant to the ConOps (e.g. hail, ice, snow, electro-magnetic interference) do not violate the independence claims, if any.</li> </ul>	Same as Low. In addition, the level of integrity claimed is substantiated by analysis and/or test data with supporting evidence.	Same as Medium. In addition, a competent third party validates the level of integrity claimed.
		Comments	N/A	N/A	N/A

# 6. Deterioration of external systems supporting UAS operation

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

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	Criteria	<ul> <li>The applicant ensures that the level of performance for any externally provided service necessary for the safety of the is adequate for the intended operation.</li> <li>If the externally provided service requires communication between the operator and service provider, the applicant entere is effective communication to support the service provisions.</li> <li>Roles and responsibilities between the applicant and the external service provider are defined.</li> </ul>		
operations are adequate to the operation	Comments	N/A	N/A	Requirements for contracting services with Service Provider may be derived from ICAO Standards and Recommended Practices - SARPS (currently under development).

DETERIOR			LEVEL of ASSURANCE	
EXTERNAL SYSTEMS SUPPORTING UAS OPERATION BEYOND THE CONTROL OF THE UAS		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 for any externally provided service required for safety of the flight 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.	<ul> <li>Same as Medium. In addition:</li> <li>The evidence of the externally provided service performance is achieved through demonstrations.</li> <li>A competent third party validates the claimed level of integrity.</li> </ul>
	Comments	N/A	N/A	N/A

### 7. Human Error

#### OSO #16 - Multi crew coordination

HUMAN ERROR			LEVEL of INTEGRITY	
HUMAN	ERROR	Low	Medium	High
	Criterion #1 (Procedures)	<ul> <li>Procedure(s) to ensure coordination betwavailable and at a minimum cover:</li> <li>assignment of tasks to the crew,</li> <li>establishment of step-by-step comm</li> </ul>	ween the crew members and robust and eff unications. <sup>1</sup>	fective communication channels is (are)
	Comments	<sup>1</sup> The distinction between a low, a mediul assurance (see table below).	m and a high level of robustness for this cr	iterion is achieved through the level of
	Criterion #2 (Training)	Remote Crew training covers multi crew coordination	Same as Low. In addition, the Remote Crew <sup>2</sup> receives Crew Resource Management (CRM) <sup>3</sup> training.	Same as Medium.
OSO #16 Multi crew coordination	Comments	N/A	<ul> <li><sup>2</sup> In the context of SORA, the term "Remote crew" refers to any person involved in the mission.</li> <li><sup>3</sup> 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.</li> </ul>	N/A
	Criterion #3 (Communication devices)	N/A	Communication devices comply with standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority <sup>4</sup> .	Communication devices are redundant <sup>5</sup> and comply with standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority <sup>6</sup> .
	Comments	N/A	<sup>4</sup> National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	<ul> <li><sup>5</sup> This implies the provision of an extra device to cope with the failure case of the first device.</li> <li><sup>6</sup> National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.</li> </ul>

HUMAN ERROR			LEVEL of ASSURANCE	
HOWAN	ERROR	Low	Medium	High
OSO #16 Multi	Criterion #1 (Procedures)	<ul> <li>Procedures do not require validation against either a standard or a means of compliance considered adequate by the competent authority.</li> <li>The adequacy of the procedures and checklists is declared.</li> </ul>	<ul> <li>Procedures are validated against standards considered adequate by the competent authority and/or in accordance with means of compliance acceptable to that authority<sup>1</sup>.</li> <li>Adequacy of the procedures is proven through:         <ul> <li>Dedicated flight tests, or</li> <li>Simulation, provided the simulation is proven valid for the intended purpose with positive results.</li> </ul> </li> </ul>	<ul> <li>Same as Medium. In addition:</li> <li>Flight tests performed to validate the procedures cover the complete flight envelope or are proven to be conservative.</li> <li>The procedures, flight tests and simulations are validated by a competent third party.</li> </ul>
crew coordination	Comments	N/A	<sup>1</sup> National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	N/A
	Criterion #2 (Training)	Training is self-declared (with evidence available)	<ul> <li>Training syllabus is available.</li> <li>The operator provides competency-based, theoretical and practical training.</li> </ul>	<ul> <li>A competent third party:</li> <li>Validates the training syllabus.</li> <li>Verifies the remote crew competencies.</li> </ul>
	Comments	N/A	N/A	N/A

HUMAN ERROR		LEVEL of ASSURANCE			
HOWAN	ERROR	Low	Medium	High	
Criterion #3 (Communication devices)		Consider the criteria defined in section 9			
	Comments	N/A	N/A	N/A	

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

- (a) For the purpose of this assessment, the expression "fit to operate" should be interpreted as physically and mentally fit to perform duties and discharge responsibilities safely.
- (b) Fatigue and stress are contributory factors to human error. Therefore, to ensure vigilance is maintained at a satisfactory level of safety, consideration may be given to the following:
  - Remote Crew duty times;
  - Regular breaks;
  - Rest periods;
  - Handover/Take Over procedures.

HUMAN ERROR		LEVEL of INTEGRITY		
	ERROR	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.	<ul> <li>Same as Low. In addition:</li> <li>Duty, flight duty and resting times for the remote crew are defined by the applicant and adequate for the operation.</li> <li>The operator defines requirements appropriate for the remote crew to operate the UAS.</li> </ul>	<ul> <li>Same as Medium. In addition:</li> <li>The remote crew is medically fit,</li> <li>A Fatigue Risk Management. System (FRMS) is in place to manage any escalation in duty/flight duty times.</li> </ul>
	Comments	N/A	N/A	N/A

HUMAN ERROR			LEVEL of ASSURANCE	
HUMAN		Low	Medium	High
OSO #17 Remote crew is fit to operate	Criteria	<ul> <li>The policy to define how the remote crew declares themselves fit to operate (before an operation) is documented.</li> <li>The remote crew declaration of fit to operate (before an operation) is based on policy defined by the applicant.</li> </ul>	<ul> <li>Same as Low. In addition:</li> <li>Remote crew duty, flight duty and the resting times policy is documented.</li> <li>Remote crew duty cycles are logged and cover at minimum: <ul> <li>when the remote crew member's duty day commences,</li> <li>when the remote crew members are free from duties,</li> <li>resting times within the duty cycle.</li> </ul> </li> <li>There is evidence that the remote crew is fit to operate the UAS.</li> </ul>	<ul> <li>Same as Medium. In addition:</li> <li>Medical standards considered adequate by the competent authority and/or means of compliance acceptable to that authority<sup>1</sup> are established and a competent third party verifies the remote crew is medically fit.</li> <li>A competent third party validates the duty/flight duty times.</li> <li>If a FRMS is used, it is validated and monitored by a competent third party.</li> </ul>
	Comments	N/A	N/A	<sup>1</sup> National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.

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

- (a) Unmanned Aircraft (UA) are designed with a flight envelope that describes its safe performance limits with regard to minimum and maximum operating speeds, and operating structural strength.
- (b) Automatic protection of the flight envelope is intended 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.
- (c) 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).
- (d) 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.
- (e) Failures or development errors of the flight envelope protection are addressed in OSOs #5, #10 and #12.

HUMAN	EPPOP	LEVEL of INTEGRITY		
HOWAN	ERROR	Low	Medium High	
OSO #18 Automatic protection of the flight envelope from human errors	Criteria	The UAS flight control system incorporates automatic protection of the flight envelope to prevent the remote pilot from making any <u>single</u> input under <u>normal operating conditions</u> that would cause the UA to exceed its flight envelope or prevent it from recovering in a timely fashion.	The UAS flight control system incorporate envelope to ensure the UA remains withi recovery to the designed operational fligh <u>error(s)</u> . <sup>1</sup>	n the flight envelope or ensures a timely
	Comments	N/A	<sup>1</sup> The distinction between a medium and a is achieved through the level of assurance	a high level of robustness for this criterion e (see table below).

			LEVEL of ASSURANCE		
HOWAN		Low	Medium	High	
OSO #18 Automatic protection of the flight	<ul> <li>Criteria</li> <li>Criteria</li> <li>Criteria</li> <li>Criteria</li> <li>Component Off The Shelf elewithout following specific state</li> </ul>	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 to standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority.	Same as Medium. In addition, evidence is validated by a competent third party.	
envelope from human errors	Comments	N/A	National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	N/A	

#### OSO #19 - Safe recovery from Human Error

- (a) This OSO addresses the risk of human errors which may affect the safety of the operation if not prevented or detected and recovered in a timely fashion.
  - i) Errors can be from anyone involved in the operation
  - ii) 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.
  - iii) 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 it is specifically covered by OSO #18.

- (b) This OSO covers:
  - i) Procedures and lists,
  - ii) Training, and
  - iii) UAS design, i.e. systems detecting and/or recovering from human errors (e.g. safety pins, use of acknowledgment features, fuel or energy consumption monitoring functions ...)

	EPPOP	LEVEL of INTEGRITY				
HUMAN ERROR		Low	Medium	High		
	Criterion #1 (Procedures and checklists)	<ul> <li>Procedures and checklists that mitigate the risk of potential human errors from any person involved with the mission are defined and used.</li> <li>Procedures provide at a minimum: <ul> <li>a clear distribution and assignment of tasks,</li> <li>an internal checklist to ensure staff are adequately performing assigned tasks.</li> </ul> </li> </ul>				
	Comments	N/A	N/A	N/A		
	Criterion #2 (Training)	<ul> <li>The Remote Crew<sup>1</sup> is trained to procedures and checklists.</li> <li>The Remote Crew<sup>1</sup> receives Crew Resource Management (CRM)<sup>2</sup> training.<sup>3</sup></li> </ul>				
OSO #19 Safe recovery from Human	Comments	<ul> <li><sup>1</sup> In the context of SORA, the term "Remote crew" refers to any person involved in the mission.</li> <li><sup>2</sup> 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.</li> <li><sup>3</sup>The distinction between a low, a medium and a high level of robustness for this criterion is achieved through the level of assurance (see table below).</li> </ul>				
Error	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 standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority.	Same as medium.		
	Comments	N/A	National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	N/A		

	ERROR	LEVEL of ASSURANCE		
HOMAN	ERROR	Low	Medium	High
OSO #19 Safe recovery from Human Error	Criterion #1 (Procedures and checklists)	<ul> <li>Procedures and checklists do not require validation against either a standard or a means of compliance considered adequate by the competent authority.</li> <li>The adequacy of the procedures and checklists is declared.</li> </ul>	<ul> <li>Procedures and checklists are validated against standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority<sup>1</sup>.</li> <li>Adequacy of the procedures and checklists is proven through:         <ul> <li>Dedicated flight tests, or</li> <li>Simulation provided the simulation is proven valid for the intended purpose with positive results.</li> </ul> </li> </ul>	<ul> <li>Same as Medium. In addition:</li> <li>Flight tests performed to validate the procedures and checklists cover the complete flight envelope or are proven to be conservative.</li> <li>The procedures, checklists, flight tests and simulations are validated by a competent third party.</li> </ul>
	Comments	N/A	<sup>1</sup> National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	N/A
	Criterion #2 (Training)	Consider the criteria defined for level of a OSO #22) corresponding to the SAIL of t	assurance of the generic remote crew train	ing OSO (i.e. OSO #09, OSO #15 and

	HUMAN ERROR		LEVEL of ASSURANCE			
			Low	Medium	High	
		Comments	N/A	N/A	N/A	
	Criterion #3 (UAS design)		Consider the criteria defined in section 9			
		Comments	N/A	N/A	N/A	

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

HUMAN ERROR		LEVEL of INTEGRITY		
		Low	Medium	High
OSO #20 A Human	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.		
Factors evaluation has been performed and the HMI found appropriate for the mission	naintain awareness of the position of the uring operation; g for any potential collision hazard; and			

HUMAN ERROR		LEVEL of ASSURANCE			
		Low	Medium	High	
OSO #20 A Human Factors evaluation has been	Criteria	The applicant conducts a human factors evaluation of the UAS to determine if the HMI is appropriate for the mission. The HMI evaluation is based on inspection or Analyses.	Same as Low but the HMI evaluation is based on demonstrations or simulations. <sup>1</sup>	Same as Medium. In addition, a competent third party witnesses the HMI evaluation.	
performed and the HMI found appropriate for the mission	Comments	N/A	<sup>1</sup> When simulation is used, the validity of the targeted environment used in the simulation needs to be justified.	N/A	

# 8. Adverse Operating Conditions

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

ADVERSE OPERATING CONDITIONS		LEVEL of INTEGRITY				
		Low	Medium	High		
0.00 #00	Criterion #1 (Definition)	Environmental conditions for safe operations are defined and reflected in the flight manual or equivalent document. <sup>1</sup>				
OSO #23 Environmental conditions for safe operations defined, measurable and adhered to	Comments	<sup>1</sup> The distinction between a low, a medium and a high level of robustness for this criterion 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 recording system. <sup>2</sup>				
	Comments	<sup>2</sup> The distinction between a low, a medium and a high level of robustness for this criterion is achieved through the level of assurance (see table below).				
	Criterion #3 (Training)	Training covers assessment of meteorological conditions. <sup>3</sup>				
	Comments	<sup>3</sup> The distinction between a low, a medium and a high level of robustness for this criterion is achieved through the level of assurance (see table below).				

ADVERSE OPERATING CONDITIONS		LEVEL of ASSURANCE		
		Low	Medium	High
	Criterion #1 (Definition)	Consider the criteria defined in section 9		
	Comments	N/A		
OSO #23 Environmental conditions for safe operations defined, measurable and adhered to	Criterion #2 (Procedures)	<ul> <li>Procedures do not require validation against either a standard or a means of compliance considered adequate by the competent authority.</li> <li>The adequacy of the procedures and checklists is declared.</li> </ul>	<ul> <li>Procedures are validated against standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority.</li> <li>The adequacy of the procedures is proved through:         <ul> <li>Dedicated flight tests, or</li> <li>Simulation provided the simulation is proven valid for the intended purpose with positive results.</li> </ul> </li> </ul>	<ul> <li>Same as Medium. In addition:</li> <li>Flight tests performed to validate the procedures cover the complete flight envelope or are proven to be conservative.</li> <li>The procedures, flight tests and simulations are validated by a competent third party.</li> </ul>
	Comments	N/A	N/A	N/A
	Criterion #3 (Training)	Training is self-declared (with evidence available).	<ul> <li>Training syllabus is available.</li> <li>The operator provides competency- based, theoretical and practical training.</li> </ul>	<ul> <li>A competent third party:</li> <li>Validates the training syllabus.</li> <li>Verifies the remote crew competencies.</li> </ul>
	Comments	N/A	N/A	N/A

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

- (a) To assess the integrity of this OSO, the applicant determines:
  - Can credit be taken for the equipment environmental qualification tests / declarations, e.g. by answering the following questions:
    - i. Is there a Declaration of Design and Performance (DDP) available to the applicant stating the environmental qualification levels to which the equipment was tested?
    - ii. Did the environmental qualification tests follow a standard considered adequate by the competent authority (e.g. DO-160)?iii. Are the environmental qualification tests appropriate and sufficient to cover all environmental conditions related to the ConOps?
    - iv. 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 DO-160 like tests?
  - Can the suitability of the equipment for the intended/expected UAS environmental conditions be determined from either inservice experience or relevant test results?
  - Any limitations which would affect the suitability of the equipment for the intended/expected UAS environment conditions.
- (b) The lowest integrity level should be considered for those cases where a UAS equipment has only a partial environmental qualification and/or a partial demonstration by similarity and/or parts with no qualification at all.

ADVERSE OPERATING CONDITIONS		LEVEL of INTEGRITY			
		N/A	Medium	High	
OSO #24 UAS designed and qualified	Criteria	N/A	The UAS is designed to limit the effect of environmental conditions.	The UAS is designed using environmental standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority.	
for adverse environmental conditions	Comments	N/A	N/A	National Aviation Authorities (NAAs) may define the standards and/or the means of compliance they consider adequate. The SORA Annex E will be updated at a later point in time with a list of adequate standards based on the feedback provided by the NAAs.	

ADVERSE OPERATING CONDITIONS		LEVEL of ASSURANCE		
		N/A	Medium	High
OSO #24 UAS designed	Criteria	N/A	Consider the criteria defined in section 9	
and qualified for adverse environmental conditions	Comments	N/A	N/A	

# 9. Assurance level criteria for technical OSO

		LEVEL of ASSURANCE		
		Low	Medium	High
TECHNICAL OSO	Criteria	The applicant declares that the required level of integrity has been achieved <sup>1</sup> .	The applicant has supporting evidence that the required level of integrity is achieved. This is typically done by testing, analysis, simulation <sup>2</sup> , inspection, design review or through operational experience.	A competent third party validates the claimed level of integrity.
	Comments	<sup>1</sup> Supporting evidence may or may not be available	<sup>2</sup> When simulation is used, the validity of the targeted environment used in the simulation needs to be justified.	N/A