Implementation of SORA Methodology Version 2.5 for Medical Delivery Using Quadrotor UAS in Remote Areas

Rachmad Hidayat*[1,2], Yazdi Ibrahim Jenie[1]

[1]Faculty of Mechanical and Aerospace Engineering - Institut Teknologi Bandung
ITB Kampus Ganesha Jl. Ganesha 10 (Bandung, Indonesia)
[2]Advanced Master in Unmanned Aircraft System, Service and Management - Ecole Nationale de l'Aviation Civile
7, Avenue Edouard Belin (Toulouse, France)

E-mail: *jrhidayat03@gmail.com

Diterima: 17 Januari 2023, disetujui: 27 November 2023, diterbitkan online: 29 Desember 2023

Abstract

The innovative quadrotor Unmanned Aircraft Systems (UAS) approach for delivery missions presents significant opportunities to address logistical distribution challenges (i.e. medical delivery) in remote areas. The efficiency of quadrotor UAS, which does not need additional infrastructure like runways, makes it increasingly applicable to remote regions. However, the potential implementation of UAS for medical delivery missions comes with considerable risks, such as collisions with manned aircraft or UAS crashes that could damage infrastructure and cause fatal injuries to human life. Therefore, in UAS operations, a method of operational risk assessment is needed to ensure safety, resilience, and operational success. The Joint Authorities for the Rulemaking of Unmanned Systems (JARUS) offers a risk assessment methodology named Specific Operational Risk Assessment (SORA) for UAS operations. The European Union Aviation Safety Agency (EASA) and the Indonesian Ministry of Transportation have recognised and approved this methodology as a risk assessment method for specific UAS categories. SORA provides a step-by-step framework in risk assessment to identify, evaluate, and determine necessary mitigation actions to achieve an acceptable means of compliance (MoC). EASA has announced using the latest version, SORA V2.5, planned for implementation in the fourth quarter of 2023. The Indonesian Ministry of Transportation also plans to adopt this latest version for UAS operations. Several updates and simplifications have been made to this version. Therefore, this paper presents the application of risk assessment using SORA V2.5 for medical delivery operations in remote areas using quadrotor UAS. The analysis in this paper covers each step of SORA V2.5, including risk identification and evaluation, as well as the implementation of mitigations in the conducted mission. The results indicate that SORA V2.5 can be implemented in this mission by taking appropriate mitigation actions to assure operational safety. There are also recommendations for optimising risk identification and it can complement the SORA methodology.

Keywords: Medical Delivery, Risk Assessment, Remote Area, SORA Methodology, Unmanned Aerial System (UAS)

Abstrak

Implementasi Metodologi SORA Versi 2.5 untuk Pengiriman Medis Menggunakan Quadrotor UAS di Daerah Terpencil: *Pendekatan inovatif menggunakan Sistem Pesawat Tanpa Awak (UAS) quadrotor untuk misi pengiriman menawarkan peluang yang sangat baik untuk mengatasi tantangan distribusi logistik khususnya pengiriman medis di area terpencil. Efisiensi yang ditawarkan oleh UAS berjenis quadrotor, tanpa memerlukan infrastruktur tambahan seperti runway, menjadikannya semakin applicable untuk area terpencil. Di sisi lain, potensi pengimplementasian UAS untuk misi pengiriman medis ternyata membawa dampak risiko yang cukup besar, seperti tabrakan dengan pesawat terbang atau jatuhnya UAS yang dapat menyebabkan kerusakan infrastruktur dan bahaya kematian bagi manusia. Maka dari itu, dalam opersional UAS perlu dilakukan suatu metode penilaian risiko operasional untuk menjamin keselamatan, ketangguhan, dan keberhasilan operasional UAS. The Joint Authorities for the Rulemaking of Unmanned Systems (JARUS) menawarkan suatu metodologi penilaian risiko yang bernama SORA (Specific Operational Risk Assessment) untuk operational UAS. Metodologi ini telah diakui dan disahkan oleh European Union Aviation Safety Agency (EASA) dan Kementerian Transportasi Republik Indonesia sebagai suatu metode penilaian risiko untuk operasional UAS pada kategori spesifik. Metodologi SORA menawarkan kerangka kerja atau prosedur langkah demi langkah dalam penilaian risiko yang bertujuan untuk mengidentifikasi risiko, mengevaluasi risiko, dan menentukan tindakan mitigasi yang diperlukan untuk mencapai tingkat risiko yang dapat diterima pada operasi UAS yang akan dilakukan dan dapat digunakan dalam memenuhi persyaratan keselamatan (Acceptable Means of Compliance (MoC)). EASA telah mengumumkan penggunaan SORA versi terbaru, SORA V2.5, yang direncanakan akan diimplementasikan pada quarter ke-4 tahun 2023. Begitupula Kementerian Perhubungan Republik Indonesia yang akan segera menerapkan versi terbaru tersebut untuk operasional UAS di wilayah Indonesia. Beberapa pembaruan dan penyederhanaan telah dilakukan pada versi ini. Maka dari itu, karya yang disajikan dalam makalah ini adalah penerapan penilian risiko SORA V2.5 untuk operasi pengiriman medis di wilayah terpencil menggunakan UAS berjenis quadrotor. Pada makalah ini dilakukan analisis pada setiap langkah SORA V2.5 yang termasuk di dalamnya identifikasi dan evaluasi risiko serta penerapan mitigasi pada misi yang dilaksanakan. Hasil yang didapat menunjukan bahwa dalam misi ini, SORA V2.5 dapat diimplementasikan dengan melakukan tindakan mitigasi yang sesuai dengan misi sebagai jaminan pemenuhan keselamatan operasional. Terdapat juga saran dalam pengoptimalisasian identifikasi risiko untuk melengkapi metodologi SORA.*

Kata Kunci**:** *Area Terpencil, Pengiriman Medis, Penilaian Risiko, Metodologi SORA, UAS*

1. Introduction

Rapid advances in Unmanned Aircraft Systems (UAS) technology, commonly known as “drones”, have had a significant impact on the use of UAS in various fields, such as inspection [1] as well as surveillance and delivery missions [2]. Utilising UAS for delivery missions has significant advantages

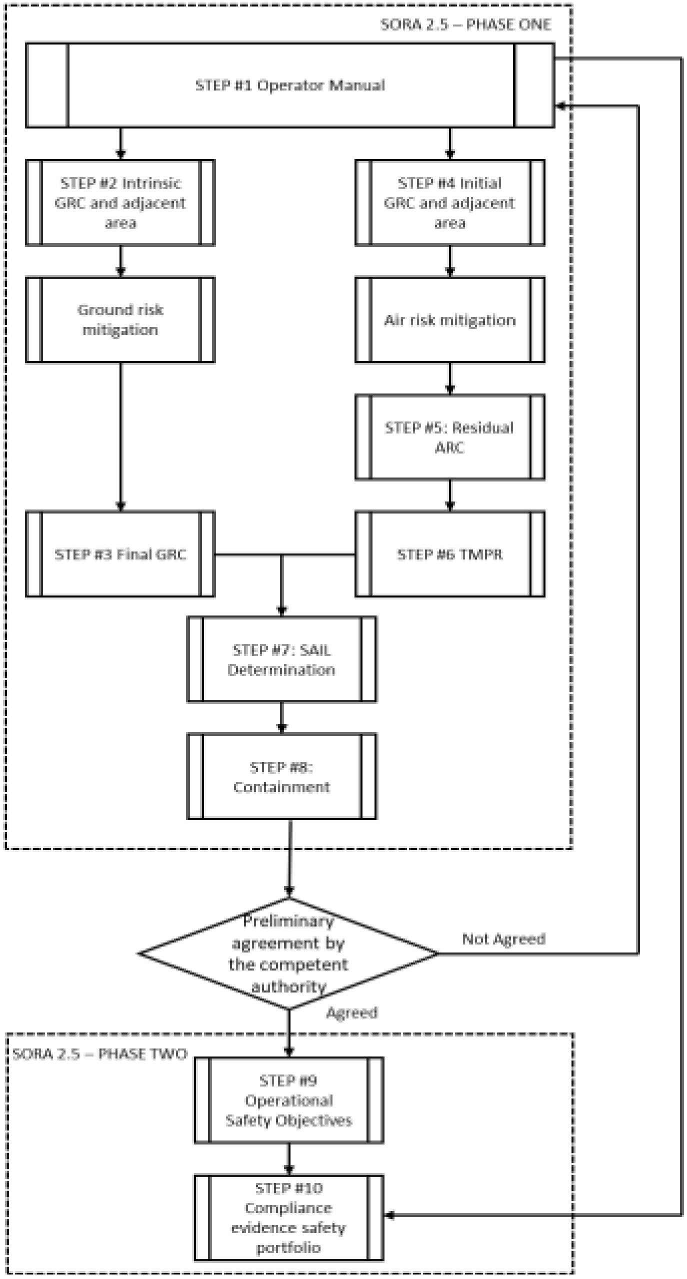
doi: http://dx.doi.org/10.25104/warlit.v35i2.2306
0852-1824/ 2580-1082
Nomor akreditasi: (RISTEKDIKTI) 10/E/KPT/2019 (Sinta 2).

over fixed-wing UAS. UAS does not require additional infrastructure, such as runways for take-off. In addition, UAS offer efficient solutions that can potentially reduce the cost and time factors of distribution. Based on these advantages, UAS can be used as an alternative solution for logistics delivery missions, such as medical supplies and necessities in remote areas due to the economic, health, infrastructure, and logistics distribution challenges that can be present in remote areas. However, despite the advantages, one of the most critical issues in UAS operations is operational safety associated with risk factors in each operation. Hence, a risk assessment needs to be performed. Three types of risks during a UAS-assisted mission [3]: 1) fatal injuries to third parties on the ground; 2) collision with third parties in the air; and 3) damage to critical infrastructure.

The European Union Aviation Safety Agency (EASA) plays an essential role in defining and regulating the design, certification, and operation of UAS. In 2019, EASA published Basic Regulation EU 2018/1139 [4], which consists of two EU regulations, including Commission Delegated Regulation (EU) 2019/945 and Commission Implementing Regulation (EU) 2019/947. The primary purpose is to standardise UAS operation regulations and separate the domain of UAS regulations from the domain of manned aircraft regulations. In these regulations, EASA categorises UAS based on their operational risk: Open (low level risk), Specific (medium level risk), and Certified (high level risk). General criteria for Open category are MTOW <25 kg, operating in VLOS, does not carry dangerous goods or drop anything, and not require approval of operations from the National Aviation Authority (NAA). When at least one of the general criteria of the Open category is not met, the UAS operation goes to a Specific or Certified type, for example, when UAS is operating in BVLOS or carrying a payload such as a delivery mission.

In the Specific category, operators must conduct a risk assessment of UAS flight operations before conducting the operations. For the risk assessment, EASA has simplified SORA for some Concepts of Operations (CONOPS), known as Pre-defined Risk Assessment (PDRA) and Standard Scenarios (STS) [4]. These two methodologies can carry out risk assessments for specific categories if the CONOPS meets the criteria required in both methods. Besides that, to streamline the authorisation procedure, Joint Authorities for the Rulemaking of Unmanned Systems, known as JARUS, has created a specific UAS operational risk assessment methodology, namely the SORA (Specific Operational Risk Assessment) methodology [4]. SORA has been recognised and approved by EASA as a risk assessment method for UAS operations for specific categories that PDRA or STS cannot cover. The SORA methodology [4] is a framework or step-by-step procedure for the risk assessment CONOPS (as seen in Figure 1). Its goal is to identify and evaluate risks associated with ground risk and air risk, and then determine the mitigation actions needed to achieve the desired risk level known as SAIL (Specific Integrity and Assurance Level). The SAIL will assist in identifying level of robustness associated with operational safety objectives, as known as OSOs (Operational Safety Objectives). So far, JARUS has released three version of SORA: 1) SORA V1.0 in 2017 (does not exist anymore); 2) SORA V2.0 in 2019 with the code JAR-DEL-WG6-D.04 [5]; and 3) SORA V2.5 (Draft for External Consultation: JARUS guidelines on SORA version 2.5 has been released for public consultation (Edition Date 08 November 2022) with implementation planned for the 4th quarter of 2023 [6].

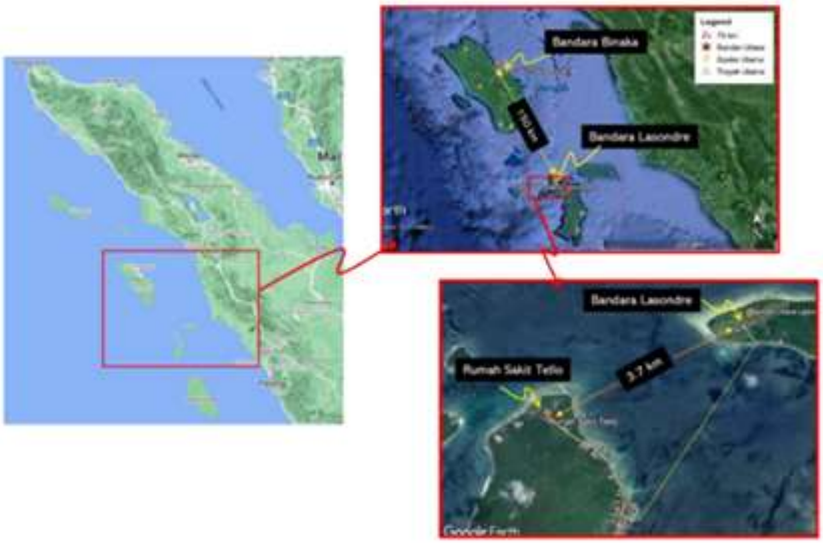
On the other hand, in Indonesia, the operator’s obligation to conduct a risk assessment on UAS operations in specific category (i.e. delivery mission operation) has been implemented in the Regulation of the Minister of Transportation of the Republic of Indonesia Number PM 37 of 2020 concerning the Operation of Unmanned Aircraft in the Airspace served by Indonesia. The regulation states: “Operation of unmanned aircraft weighing below 55 lbs for commercial purposes must obtain a safety assessment from the Director General” [7]. Based on information obtained from the Directorate of Airworthiness and Aircraft Operation (DKUPPU), the Directorate in the Ministry of Transportation that handles UAS, it is stated that the risk assessment for UAS operations adopts the SORA methodology because Indonesia is a member of JARUS. However, until this paper is written, the regulations related to risk assessment are only in draft form (SORA V2.5) and are in the process of being approved. Thus, during the regulatory approval period, every operator who will plan UAS operations in the territory of Indonesia is still required to implement the risk assessment process stage using the SORA methodology (in this case, SORA V2.0) before starting operations.



Source: [5]

Figure 1. SORA's Steps Version 2.5.

To this point, several research studies associated with risk assessment using the SORA methodology have been applied in various fields, such as those conducted by Martinez et al. [8]. Their research adapted SORA V2.0 [5] for multi-UAS risk assessment in airport airframe inspections, addressing its limitations. As a result, the modified methodology enables effective risk assessment with added mitigation measures. On the other hand, Capitan et al. Capitan et al. used SORA V1.0 for risk assessment in multi-UAS cinematography missions for rowing and cycling events in rural areas [9]. As a result, the researcher suggested that the SORA methodology be developed for comprehensive coverage of associated risks multi-UAS. In addition, research done by Shao [10] emphasized UTM infrastructure, population density, and flight certification for safe UAS logistics delivery in Taiwan, supporting their efficient use despite slightly higher risk than manned aircraft. As a result, this research supports using UAS for logistics delivery services in Taiwan, demonstrating that an adequate UTM infrastructure can ensure safe and efficient operations. However, these research studies are limited to the use of SORA V1.0 and V2.0. Research implementing the SORA V2.5 methodology for risk assessment on medical delivery missions has never been done, even though the latest version of SORA has several changes that provide simplicity and benefits for operators [11] in identifying, evaluating, and determining mitigation in terms of risk, especially for ground risk. Thus, there is a question of how SORA V2.5 can be implemented and provide safety assurance for medical delivery missions using quadrotor UAS in remote areas.



Source: [12]

Figure 2. One of the areas identified as a remote area in the research by Jenie et al. (Batu and Hinako islands) and its air route illustrations

This paper will examine the implementation of the SORA V2.5 methodology **Error! Reference source not found.** to risk assessment medical delivery missions using a UAS quadrotor in a remote area. Figure 2 shows the location map of West and South Nias Islands - North Sumatra; from Lasondre Airport as a logistics centre (hub) to Tello Hospital located west of the airport as a vaccine delivery location (spoke) [12], which will be used as use cases in this research. This location representing a remote area as described by Jenie et al. in their research [12]. In addition, Jenie et al. [12] highlight the UAS benefits for inter-island operations, particularly in distributing crucial medical materials, such as medical drugs, blood, vaccines, and sampling tests [13]. It can be an alternative to optimising intra- and inter-island connectivity with growth centres that rely only on sea and land routes. Also, based on their research, a simulation of vaccine distribution operations using UAS has been performed in this location. However, a risk assessment of the operation has not been conducted in their research. Thus, it is unknown if the mission can be implemented following applicable regulations related to UAS operations in Indonesia since, according to the regulations of the Ministry of Transportation of the Republic of Indonesia, the use of UAS for delivery mission falls into a specific category and needs to be risk assessed to ensure operational safety. Therefore, the SORA Methodology V2.5 [5] will be used to assess risk to assure operational safety for the medical delivery mission at this location. The primary objective of this research is to provide a comprehensive overview of the steps of implementing the SORA V2.5 methodology for risk assessment, that is, identifying risks, evaluating risks, and determining mitigations on medical delivery missions using quadrotor UAS in remote areas and providing an overview of risk assessment that can be used as input for the Indonesian Ministry of Transportation in evaluating UAS operations in Indonesia.

2. Research Methodology

This research conducted a study to examine the implementation of the SORA V2.5 methodology [5] for risk assessment in medical delivery missions using a UAS quadrotor in West and South Nias Islands region, North Sumatra, Indonesia. This location represents remote areas based on research conducted by Jenie et al. [12].

Data collection was conducted using a literature review. The UAS to be applied for this mission aligns with Versatyl and was created by a UAS design and manufacturing company called Skydrone Robotics in La Rochelle, France [14] (Figure 3). This selection is justified by the Versatyl's capabilities, relating to its patented modular design that allows engine changes in minutes without tools. This adaptability enables customising performance to operational needs, including changing the number of propellers and adjusting battery capacity. The UAS features a geocaging system, ensuring it stays within its operational volume during flight and is capable of automated and autonomous flight. Versatyl is 3 meters wide and offers a payload carrying capacity of up to 35 kg. At maximum payload, it can fly between 12 to 15 minutes and cover a round-trip distance of 5 km. Furthermore, allegedly from its website www.skydrone-robotics.com, Verstyl has joined the DRONE FOR LIFE consortium and, in partnership with major healthcare players [14].

Sources: [14][15]

Figure 3. (a) Versatyl flying Mule/Cargo and (b) Versatyl Medical Delivery

A Pre-application Evaluation is also conducted to identify potential conditions or limitations that require further risk assessment using the SORA V2.5 methodology [5]. The ultimate goal is to ensure that the level of risk to the medical delivery mission is acceptable and take mitigation measures where necessary to minimise the impact of potential risks. Figure 4 shows the research methodology in this paper.

2.1. Study Literature

Study literature in the form of a review of existing research papers and regulations, along with the application form for the research was carried out. This is done so that the problems faced can be understood and on target. The objects to be studied in this research are Unmanned Aircraft Systems (UAS), risk assessment, SORA meteorology, and delivery based on UAS.

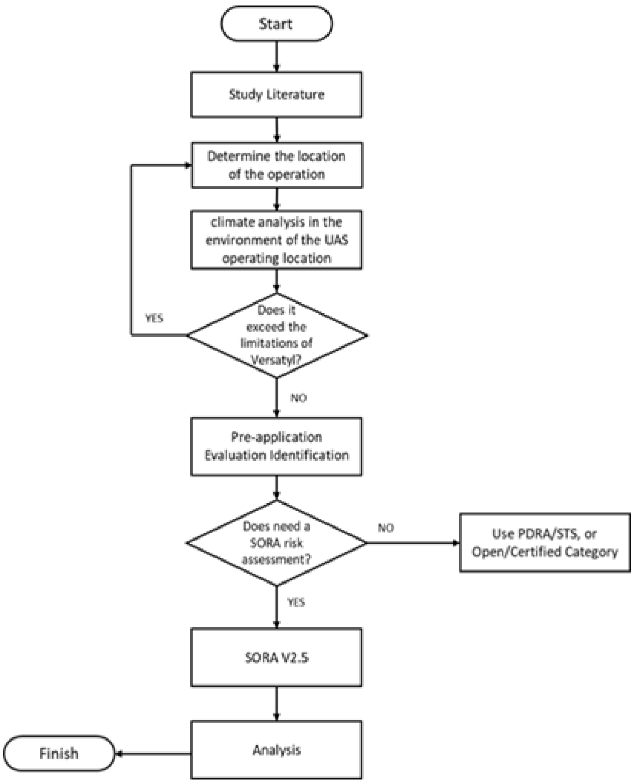


Figure 4. Research Methodology

2.2. Climate Analysis in the Environment of the UAS Operating Locations

Based on the BPS statistics report [16], Table 1 shows the minimum and maximum weather properties for each month.

Table 1. Average Weather Properties per Month

	Temperature (ºC)		Humidity (%)		Wind Velocity (knot)	
	Min	Max	Min	Max	Min	Max
January	21.3	33.6	63.0	100.0	0.0	13.0
February	20.2	34.2	47.0	100.0	0.0	15.0
March	20.8	34.0	54.0	100.0	0.0	13.0
April	21.2	34.0	48.0	100.0	0.0	13.0
May	22.7	33.5	62.0	100.0	0.0	15.0
June	21.6	31.9	62.0	100.0	0.0	15.0
July	22.1	32.8	63.0	100.0	0.0	22.0
August	22.0	32.2	64.0	100.0	0.0	16.0
September	21.6	32.0	65.0	100.0	0.0	16.0
October	20.4	32.0	64.0	100.0	0.0	17.0
November	22.4	31.4	66.0	100.0	0.0	15.0
December	22.4	32.6	58.0	100.0	0.0	12.0

Source: [16]

As a result, when a comparison is made among Verstyl's specifications, the weather at the flight site does not affect Versatyl's performance so that Versatyl can execute its mission.

2.3. Pre-application Evaluation

The identification process involves the analysis of the CONOPS for the mission, as described in Table 3, which includes the type of UAS operation (BVLOS or VLOS), mission specifications, operational constraints, and UAS specifications. The main objective is categorising whether the CONOPS falls into the Open, Specific, or Certified category. This is a critical distinction due to not all CONOPS in the specific category are covered by PDRA and STS, requiring a comprehensive risk assessment using the SORA methodology.

The literature review highlighted that the VLOS type of operation falls under the Open category [4], in stark contrast to the BVLOS flight rules applied in the Versatyl UAS CONOPS. This mismatch firmly places the CONOPS on this mission into the Specific category. Table 2 shows the pre-application evaluation results. A detailed evaluation of the PDRA and STS operational condition requirements [4] against the CONOPS specifications for this mission (Table 3) revealed non-conformities with several essential criteria, including STS-01, STS-02, PDRA-S01, PDRA-S02, PDRA-G01, PDRA-G02, and PDRA-G03. These nonconformities highlighted deviations from established standards, such as BVLOS operation types and autonomous or automated flight.

Table 2. Average Weather Properties per Month

	CONOPS Requirement [4]	CONOPS Use Case
STS-01	VLOS	BVLOS
STS-02	BVLOS max 2 km	BVLOS 3.7 km
PDRA-S01	VLOS	BVLOS
PDRA-S02	BVLOS max 2 km	BVLOS 3.7 km
PDRA-G01	Uncontrolled airspace	Controlled airspace
PDRA-G02	Uncontrolled airspace	Controlled airspace
PDRA-G03	altitude < 50 m	altitude > 50 m

As a result, it became clear that neither the PDRA nor the STS adequately covered the specifications and requirements of the Versatyl UAS operational plan. The SORA methodology, SORA 2.5 [5], was identified as an appropriate framework for a comprehensive CONOPS risk assessment.

3. SORA V2.5 Analysis and Result

A category-specific customised Specific Operations Risk Assessment (SORA) is a comprehensive and systematic methodology designed to evaluate and manage risks associated with specific UAS operations. The same with previous versions, Ver 1.0 and Ver 2.0, SORA methodology Version 2.5 is a framework or step-by-step procedure to risk assessment. The objective is to perform an accurate CONOPS risk assessment within the regulatory framework, i.e. identify and evaluate the risks in terms of ground risks and airborne risks and determine the mitigation measures required to achieve the desired risk level known as SAIL (Specific Integrity and Assurance Level). The determination of SAILs will assist in identifying the level of resilience associated with operational safety objectives, known as OSOs (Operational Safety Objectives).

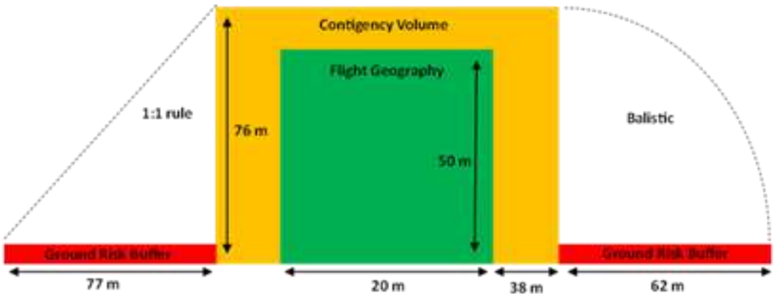
3.1. *Step 1: Documentation of the proposed operation(s); CONOPS*

The first step of SORA is to conduct a Concept of Operation (CONOPS). It means that the applicant should provide the information in terms of operation relevant information and the technical relevant information needed to assess the risk associated with the intended operation of the UAS. The main purpose of CONOPS is to describe UAS operations in detail and should cover all activities, including the operator's operational safety culture, procedure to communicate with the air navigation system provider, and emergency response plan that will be taken to manage and minimise risk in medical delivery mission. The CONOPS identifies the operational objectives of the UAS. Therefore, when defining CONOPS, the applicant should ensure all SORA's step, including mitigation and operational safety must be considered. Table 3 describes CONOPS for this mission, including specific details on the area of operation, timing, type of operation (BVLOS or VLOS), and the nature of the mission to be performed.

Table 3. CONOPS of UAS Medical Delivery

Operation Mission	Medical delivery
Category (EASA)	Specific
Location	West and South Nias Islands - North Sumatra, specifically: Between Batu Island (delivery centre from Lasondre Airport) and Telo Island (delivery target located at Tello Hospital)
Type of Airspace	Controlled
Type of Operations	BVLOS
Population Density	93 ppi/km^2 (Sparsely Populated)
Flight Condition	Morning to afternoon with good weather conditions
Operation Distance	3.7 km
Mode of Operation	Automatic or autonomous
UAS Type	Quadrotor
UAS Name	Versatyl
UAS Dimension	3m x 0.62m
Max MTOW	60 kg (max payload 35 kg)
Max Speed	15m/s – 16m/s
Max Payload	35 kg
Operating Altitude	20 m – 120 m (average altitude 50 m)

Source: www.earth.google.com
Figure 5. Path of the Mission



Source: [17]
Figure 6. Sematic Model for the Mission

Figure 5 describes the path of the mission, in which Versatyl will fly carrying medical supplies from the takeoff point (Landrose airport) to the landing point (a field near Tello hospital). During the flight, type of operation (BVLOS) will be used, the UAS will fly at an altitude of 20 m - 120 m (average altitude 50 m) and stay within the pre-calculated operational volume [17], as shown in Figure 6. The operational volume is defined as the operations under control, which is the combination of flight geography and contingency volume.

The green colour represents the Flight geography where the UAS will operate in this area. UAS operations are normal or under control as long as the UAS is flying in this green area. Standard operating procedures are used during operations in this area. If the UAS flies in the orange area, the contingency procedure will be activated to prevent loss of control of the UAS during operations. In this orange area, the UAS operation is in an abnormal situation but is still in a controlled operational category so it is necessary to take precautions so that the UAS can return to its operating area (green area).

3.2. *Step 2: Determination of the Intrinsic UAS Ground Risk Class (GRC) and Adjacent Area*

The Intrinsic UAS Ground Risk Class (GRC) relates to the risk of UAS crash on the people (in cases where UAS operations are out of control), and no mitigation is in place. When determining the Intrinsic GRC (iGRC), three parameters are taken into account: the dimensions of the UAS, the maximum speed of the UAS, and the maximum population density in the area of operation [5]. The table showing the Intrinsic Ground Risk Class (GRC) Determination in document SORA 2.5 will be used for calculation [5]. As the result of the medical delivery using UAS Versatyl in Nias Island, the iGRC result is = 2 with parameters based on Table 4.

Table 4. Parameter iGRC Calculation

	Use Case
Type of Operation	BVLOS Controlled ground Area
Dimension of UAS	3 m
Speed of UAS	15 m/s
Population Density	Sparsely Population (93 ppi/km^2)

Table 5. GRC Mitigation

	Level of Robustness		
Mitigations for ground risk	Low	Medium	High
M1(A) - Strategic mitigations for ground risk	-1	-2	-3
M1(B) - Visual Line of Sight (VLOS) – avoid flying over people	-1	N/A	N/A
M2 - Effects of UA impact dynamics are reduced	0	-1	-2/-3

Source: **Error! Reference source not found.**

In addition, determination of the adjacent area was conducted which models the area or volume where the UAS can fly or fall after the UAS experiences a flyaway condition. The adjacent area distance is calculated from the outer edge of the operational volume using the 3-minute formula multiplied by the maximum speed of the UAS (or max 5 km adjacent area). The result of adjacent area for this mission is 2.7 km.

3.3. *Step 3: Final GRC Determination*

Mitigation can be applied at this stage (if the operator feels that the iGRC value is too high and mitigation is needed to reduce the risk in the ground area on the mission). The level of robustness value for each mitigation obtained will be used as a deduction from the previously obtained iGRC so that a decrease in the risk value can occur. The final value of the reduction result is called the Final GRC value. The Annex B document [18] is needed to fulfil the safety objective requirements described at this stage. Annex B is a document that contains a detailed explanation of what requirements must be met to achieve the desired level of robustness for each mitigation.

There are three types of mitigation defined by JARUS in SORA V2.5 [5], as shown in Table 5.

For the Versatyl UAS medical delivery mission, no mitigation was claimed because closure of the takeoff and landing sites (controlled ground area) minimised the risk of impacting the population around the area. Additionally, a risk buffer (Figure 6) was utilised at the inbound stage.

3.4. *Step 4: Determination of the Initial Air Risk Class (ARC) and Adjacent Airspace*

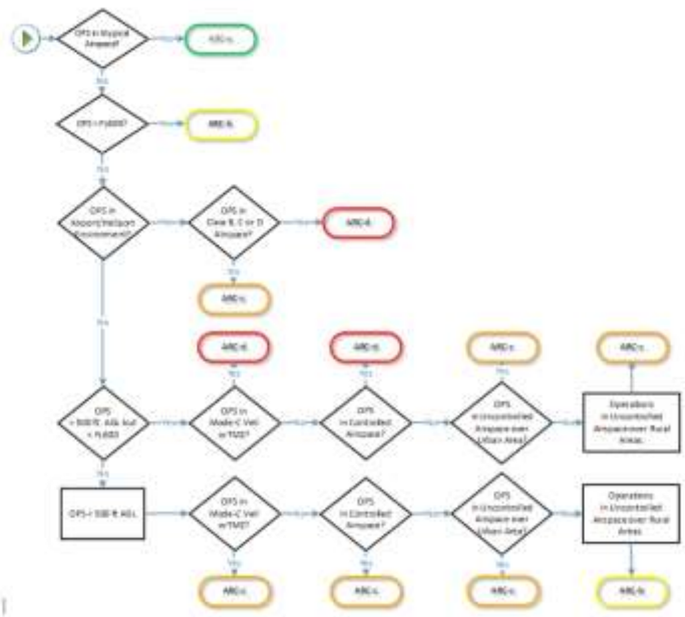
The determination aims to determine the level of risk in the airspace in UAS operations. The risk in question is a collision between UAS and aircraft or with other UAS that can result in damage or death. Figure 7 determines the areas that will be used in UAS operations, such as altitude. Will operations be carried out in controlled or uncontrolled areas? Will it be carried out in the airport or heliport area? After that, the air risk class of the operation will be known.

Based on the mission and Figure 7, the UAS will fly in the Lasondre airport area. Airspace at this airport classification is G with operational hours 01.00 - 07.00 UTC. Flights will be carried out in the morning until noon after no more flights in the airport area. The use of NOTAM is also carried out at this stage, in other words, minimising encounters between UAS carrying out missions with manned aircraft or other UAS so that the initial ARC on medical delivery UAS operations is ARC-A.

In addition, determination of adjacent airspace was conducted, and the goal is to model the area or volume where the UAS can fly or fall after the UAS experiences a flyaway condition. In the adjacent airspace, calculations are made on the lateral and vertical axes, whereas on the lateral axis, the calculation is the same as the adjacent area in GRC. In contrast, for the vertical axis, the calculation uses a 3-minute formula multiplied by the UAS climb rate (or maximum 500 m for adjacent airspace). The result of lateral adjacent airspace for this mission is 2.7 km and for vertical axis is 525.98 m or using 500 m maximum.

3.5. *Step 5: Application of Strategic Mitigations to Determine Residual ARC (optional)*

The application of strategic mitigations (Operational restrictions and Common structure) [19] aims to reduce the potential for the UAS to encounter other aircraft that can result in a collision between the two when the UAS is running its operations. Implementing this mitigation significantly impacts the initial ARC to Residual ARC (risk is reduced but not eliminated, and further mitigation must be carried out). This is because the frequency of meeting UAS with other aircraft has decreased. The Annex C document [19] is needed to fulfil the safety objective requirements described.



Source: [5]
Figure 7. Identification Process for Initial ARC

For the Versatyl UAS medical delivery mission, strategic mitigation is implemented to reduce the chance of a UAS meeting an aircraft to reduce the risk of a collision (residual ARC). Implementation of strategic mitigation was carried out, such as flying in low manned aircraft traffic conditions, flying heights below 500 ft, NOTAM, and communication procedures with navigation providers. This strategic can reduce the encounter rate of Versatyl with VFR and IFR flight or helicopter and thus, have a significant impact on reducing air risk class (residual air risk).

3.6. *Tactical Mitigation Performance Requirement (TMPR) and Robustness Levels*

The second mitigation is more technical than the first mitigation, which is strategic mitigation. TMPR aims to reduce the residual ARC done previously in Step #5 so that UAS encounters with aircraft in the UAS operational area will be reduced risk for the second time in this Step, where the final result is the Final ARC value. Table 6 shows the required TMPR level based on the residual ARC.

Based on Table 6 and that the residual ARC is ARC-a, there is no requirement for TMPR in ARC-a so no TMPR is applied in this mission.

3.7. *SAIL Determination*

Specific Assurance and Integrity Level, also known as SAIL, is an operational risk level that reflects the level of risk that UAS will face in carrying out its operations. SAIL is divided into six risk levels: SAIL I to VI, where SAIL I and II are identified as low-risk levels, SAIL III and IV are medium-risk levels, and SAIL V and IV are high-risk levels. SAIL results are very influential in fulfilling the Safety Objective Requirement that must be carried out at the next stage (specifically, the OSO stage). The parameters calculated from SAIL are the final GRC and residual ARC, as shown in Table 7.

Table 6. Safety Objective Requirement TMPR Level

Residual ARC	Tactical Mitigation Performance Requirements (TMPR)	TMPR Level of Robustness
ARC-d	High	High
ARC-c	Medium	Medium
ARC-b	Low	Low
ARC-a	No requirement	No requirement

Source: [5]

Table 7. SAIL Determination

SAIL Determation				
	Residual ARC			
Final GRC	a	b	c	d
≤ 2	I	II	IV	VI
3	II	II	IV	VI
4	III	III	IV	VI
5	IV	IV	IV	VI
6	V	V	V	VI
7	VI	VI	VI	VI
> 7	Category C (Certified) Operation			

Source: [5]

For the Versatyl UAS medical delivery mission, it is known that the result for GRC = 2 and ARC is ARC-a. So, based on Table 7, it is known that the SAIL determination on UAS Versatyl operations with a medical delivery mission in the Nias Island is SAIL = I.

3.8. *Step 8: Identification of Containment Requirements*

Identification of containment aims to address risks posed by loss of operational control (UAS flyaway) that could infringe on areas adjacent to operational volumes and risk buffers. Based on Annex E [20], two stages must be done before determining the final level of containment, including identifying the adjacent area containment for GRC and the adjacent airspace containment for ARC.

For the Versatyl UAS medical delivery mission, particularly the adjacent area containment for GRC, the Final GRC has been identified as 2, and SAIL is SAIL I, so no containment is required at GRC. Similarly, for the adjacent airspace containment for ARC, the Final ARC has been identified as ARC-a and SAIL is SAIL I. As a result, no containment is required at GRC. Based on these two results, the final containment level is “None”, meaning no containment is required.

3.9. *Identification of Operational Safety Objectives (OSO)*

The identification of OSO is performed using the SAIL results that have been obtained previously. It then identifies what requirements must be met in the OSOs and their level of robustness. These requirements were organised into 18 OSOs, each demanding a certain level of robustness (integrity and assurance) depending on the SAIL (i.e., Optional (NR/O), Low robustness (L), Medium robustness (M), and High robustness (H)). Table 8 provides a qualitative methodology for making this determination. Annex E [20] is required to meet the requirements of the safety objectives described in that document.

For the Versatyl UAS medical delivery mission identified as SAIL I, based on Table 8, 18 OSOs must be taken into account to fulfil the safety requirements, of which nine fall into the “Optional” category and nine fall into the “Low” category.

3.10. *Step 10: Comprehensive Safety Portfolio*

Based on Table 8, the robustness level requirements that must be met at SAIL I are known. In OSO, it is known that almost half of them is “Optional/O” because SAIL I is categorised as a low-risk level in the SORA risk assessment. Therefore, this stage only focuses on fulfilling the OSO robustness level requirements for the “Low/L” label. The use of the Annex E document [20] is to determine the requirements for the level of robustness (integrity and assurance) needed to fulfil the operational safety of the UAS.

- OSO #III (L)
  For integrity, the operation manual will include the procedure of how-to crew can declare him/her self if him/her is fit physically and mentally to operate and fulfil him/her responsibilities (e.g. using a checklist). For assurance, declare that policy of health and safety is documented and the procedure of the declaration of fit is documented and fit condition can be approved.

Table 8. OSO

OSO Number	Objective	SAIL I II III IV V VI	Operator	Training org.	Manufacturer
I	Ensure the operator is competent and/or proven	O L M H H H	X		
II	UAS is manufactured by competent and/or proven entity	O O L M H H			X
III	Remote crew is fit to operate	L L M M H H	X	X	
IV	Operational procedures are defined, validated and adhered to address normal, abnormal, and emergency situations potentially resulting from technical issues with the UAS or external systems supporting UAS operation, human errors, or critical environmental conditions	L M H H H H			
V	UAS is maintained by competent and/or proven entity	L L M M H H	Crit. 1 Crit. 2		Crit. 1
VI	Conformity checks of the UAS configuration	L L M M H H	Crit. 1	Crit. 2	
VII	Environmental conditions for safe operations defined, measurable, and adhered to	L L M M H H	Crit. 2	Crit. 3	Crit. 1
VIII	External services supporting UAS operations are adequate to the operation	L L M H H H	X		
IX	Multi crew coordination	L L M M H H	Crit. 1 Crit. 3	Crit. 2	
X	Remote crew trained and current and able to control the normal, abnormal, and emergency situations potentially resulting from technical issues with the UAS or external systems supporting UAS operation, human errors, or critical environmental conditions	L L M M H H		X	
XI	Safe recovery from Human Error	O O L M M H	Crit. 1 Crit. 2	Crit. 2	Crit. 3
XII	UAS components essential to safe operations are designed to an Airworthiness Design Standard (ADS)	O O O L M H			X
XIII	UAS is designed considering system safety and reliability	O O L M H H			X
XIV	Automatic protection of the flight envelope from human errors	O O L M H H			X
XV	A Human Factors evaluation has been performed and the Human-Machine Interface (HMI) found appropriate for the mission	O L L M M H			X
XVI	C3 link characteristics (e.g. performance, spectrum use) are appropriate for the operation	O L L M H H			X
XVII	UAS is designed and qualified for adverse environmental conditions (e.g. adequate sensors, DO-160 qualification)	O O M H H H			X
XVIII	Safe recovery from technical issue with the UAS or external systems supporting UAS operation	L L M M H H			X

Source: [5]

- OSO #IV (L)
  For integrity:
  1) The operation manual will include NORMAL procedures:
     - General steps that will be taken during flight planning,
     - Procedures describing how UAS is inspected before and after the flight, including the procedures that cover all phases of flight: preparation, start, take-off, climb, cruise, descent, landing, shutdown, etc.
     - Procedures on how to evaluate the environmental conditions before and during the flight in relation to operational limitations of the UAS
  2) The operation manual will include ABNORMAL procedures:
     - Low battery/fuel level
     - Limitation of an external system supporting UAS operation
     - Loss of GPS and loss of link
     - Contingency procedure, how to cope with unexpected adverse operating conditions (e.g. when ice is encountered during an operation not approved for icing conditions.
     - The procedure should describe how to ensure that no uninvolved people are overflown and how the controlled ground area is maintained
  3) The operation manual will include EMERGENCY procedures describing the operational (flight) that will be taken over manually when the UAS is controlled automatically during the flight, fire and human error, traffic interference, and flyaway/loss of flight control.

For assurance: declare that all operational procedures are tested and validated through assessments, simulations, and flight tests, proof of the adequacy of the procedures through tests or practical exercise for phases of the UAS operation other than the UA flight, which involve the UAS and/or any external system that supports the operation, a proof of the adequacy of the contingency and emergency procedures, a record of proof of the adequacy of the procedures, and all procedure (normal, abnormal, and emergency) should be validated by the operator, either through actual flight test/simulation.

- OSO #V
  For integrity, the maintenance requirements and procedures to conduct maintenance on the UAS used within the organization (based on maintenance manual from manufacturer), an internal procedure (internal audit or quality assurance system) to check the maintenance requirements and procedures based on the maintenance manual/instruction, schedule maintenance development in accordance with the maintenance program, maintenance log in which all maintenance actions are recorded, the maintenance staff is competent and has received authorization to carry out UAS maintenance, and a maintenance release should a staff member who has received a maintenance release authorization for that particular UAS model/family. For assurance: the maintenance instructions are documented, the maintenance conducted on the UAS is recorded in a maintenance log system, and a list of maintenance staff authorized to carry out maintenance is established and kept up to date.
- OSO #VI (L)
  For integrity: the procedure and checklist to check the technical condition of the UAS before each flight, schedule of the crew (operation time and flight time limitation for crew), and briefing before the flight. For assurance: declare that product inspection is documented in operation manual.
- OSO #VII (L)
  For integrity: procedure and/or information about safe operation environmental conditions (limitations) for the used UAS, procedure how to calculate/evaluate safe operation environmental conditions (limitations) before and during the flight, e.g. condition of weather and other possible sources of interface, such as a magnetic source, procedure how to assess and record the meteorological conditions during the flight, remote pilot crew is trained in terms of meteorology in which major part is to read, understand METAR information’s, and learn how to use several devices. For assurance: procedures for the determination of weather conditions are validated and proven adequate through flight tests and simulation sessions, procedures for the determination of weather conditions are validated and proven adequate through flight tests and simulation sessions, theoretical and practical training on working in compliance with the operations manual and other documentation, and the training described in documented of training syllabus.
- OSO #VIII (L)
  For integrity: regarding on externally provided service, for example coordination/communication with ATC using a mobile phone or VHF radio. For assurance: the evidence of performance is demonstrated through flight tests, and the performance of signal should be monitored in real time during the operation.
- OSO #IX (L)
  For integrity: a communication protocol, describing step-by-step standard communication/coordination between the crew members during all phases of flight. The communication/coordination which is robust and effective should be achieved by protocol, describe what responsibilities and tasks are for all crew members in the flight operation, remote crew training contains CRM training, and describe what equipment is used for communication between crew members (e.g. HT). Communication devices comply with standards considered adequate by the competent authority and/or in accordance with a means of compliance acceptable to that authority. For assurance: the required level of integrity is achieved (support with evidence), including the testing, analysis, simulation, inspection, design review or through operational experience.

- OSO #X (L)
  For integrity: include the remote pilot crew training (covers emergency and abnormal situation including theory, simulation, and real flight training). For assurance: theoretical and practical training on working in compliance with the operation manual and other documentation, the training described in documented of training syllabus, remote crew has a pilot operator's license, which is still valid. Successful replay checks extend validity for another year, and the remote pilot crew provides competency-based (theoretical and practical training).
- OSO #XVIII (L)
  For integrity: the correct setting and functioning of the external system (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), the operational volume that must be avoided due to any environmental disturbances that can affect the positioning-keeping capabilities of the UAS and/or the external system, the correct settings of the internal UAS safety systems, and 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. For assurance: a design and installation appraisal is available and a warning is issued in case of potentially exiting the operational area or flying too close to terrain.

4. Conclusions

This paper implements each risk assessment step using the SORA V2.5 methodology to identify and evaluate the risk associated with ground and air risk and determine the mitigation to reduce the impact of the risk on medical delivery missions in remote areas. In addition, this paper also presents the effects of weather properties on UAS performance at the mission location and pre-application evaluation analysis is also conducted to determine what operational categories and risk assessment methods can be used in this study. This paper also presents how CONOPS is described for medical delivery operations and how strategic actions are taken to address the integrity and assurance requirements to meet the safety objective requirement, OSO. In implementing SORA V2.5 in this use case, it was found that SORA V2.5 conducted for medical delivery missions using Versatyl in remote areas has a low-risk level, SAIL I. This is because of the low population density. This is because the low population density (sparsely populated) on the two operational islands makes it easy to control landing and flight locations (controlled ground area) so that the impact of risks on the ground can be controlled. In addition, the implementation of mitigation, especially strategic mitigation of air risks such as the use of NOTAMs and flying at very low altitudes, can reduce UAS encounters with manned aircraft in the air so that the risk of collisions can be avoided and provide safety assurance for this mission. However, additional efforts must be made to identify risks, especially on the ground, as the lack of comprehensive live population data reduces the accuracy of ground risk assessments. This, of course, will have a significant impact if UAS operations are conducted in urban areas, as it will be a challenge to use controlled ground area methods to control the location of UAS operations. In the SORA V2.5 methodology, the population density parameter is the most critical in-ground risk assessment. Therefore, the competent authority and the operator must work together to define the ground risk assessment or create a more comprehensive population assessment method. The accuracy of the ground risk assessment is critical in providing operational safety assurance for UAS in medical delivery missions and can complement the SORA V2.5 methodology.

Acknowledgement

The authors appreciate the supports from Indonesian Ministry of Transportation and Skydrone Robotics, La Rochelle, France in conducting research for this topic.

References

[1] M. Shafiee, Z. Zhou, L. Mei, F. Dinmohammadi, J. Karama, and D. Flynn, “Unmanned aerial drones for inspection of offshore wind turbines: A mission-critical failure analysis,” *Robotics*, vol. 10, no. 1, 2021, doi: 10.3390/robotics10010026.

[2] J. Koiwanit, “Analysis of environmental impacts of drone delivery on an online shopping system,” *Advances in Climate Change Research*, vol. 9, no. 3, 2018, doi: 10.1016/j.accre.2018.09.001.

[3] Jarus, *UAS Operational Categorization*. 2019. Accessed: Dec. 20, 2023. [Online]. Available: http://jarus-rpas.org/wp-content/uploads/2023/06/jar_10_doc_UAS_Operational_Cat.pdf

[4] European Union Aviation Safety Agency, “Easy Access Rules for Unmanned Aircraft Systems,” European Union Aviation Safety Agency. Accessed: Dec. 20, 2023. [Online]. Available: https://www.easa.europa.eu/en/document-library/easy-access-rules/easy-access-rules-unmanned-aircraft-systems-regulations-eu

[5] Jarus, *JARUS guidelines on Specific Operations Risk Assessment (SORA) Edition Number 2.0*. Jarus, 2019. Accessed: Dec. 20, 2023. [Online]. Available: http://jarus-rpas.org/wp-content/uploads/2023/07/jar_doc_06_jarus_sora_v2.0.pdf

[6] Jarus, *Draft For External Consultation: JARUS guidelines on Specific Operations Risk Assessment (SORA) Edition Number 2.5*. 2022. Accessed: Dec. 20, 2023. [Online]. Available: http://jarus-rpas.org/wp-content/uploads/2023/07/jar_doc_06_jarus_sora_v2.0.pdf

[7] Kementerian Perhubungan, *Peraturan Menteri Perhubungan Nomor 37 Tahun 2020 tentang Pengoperasian Pesawat Udara Tanpa Awak di Ruang Udara yang Dilayani Indonesia*. Indonesia, 2020.

[8] C. Martinez, P. J. Sanchez-Cuevas, S. Gerasimou, A. Bera, and M. A. Olivares-Mendez, “SORA Methodology for Multi-UAS Airframe Inspections in an Airport,” *Drones*, vol. 5, no. 4, p. 141, Nov. 2021, doi: 10.3390/drones5040141.

[9] C. Capitan, J. Capitan, A. R. Castano, and A. Ollero, “Risk Assessment based on SORA Methodology for a UAS Media Production Application,” in *2019 International Conference on Unmanned Aircraft Systems (ICUAS)*, IEEE, Jun. 2019, pp. 451–459. doi: 10.1109/ICUAS.2019.8798211.

[10] P.-C. Shao, “Risk Assessment for UAS Logistic Delivery under UAS Traffic Management Environment,” *Aerospace*, vol. 7, no. 10, p. 140, Sep. 2020, doi: 10.3390/aerospace7100140.

[11] Press, “Involi – what is the impact of SORA 2.5 on your Operational Authorisation application?,” sUAS News,” Suas News: The Business of Drones.

[12] Yazdi Ibrahim Jenie, Chandra Liuswanto, Mahesa Akbar, and Novyanto Widadi(, “Studi Prospektif Penggunaan Drone Kargo di Daerah Terdepan, Terpencil dan Tertinggal (3T) dan Terdampak Bencana,” *Jurnal Warta Ardhia*, vol. 48, no. 2, pp. 95–110, 2022.

[13] J. EUCHI, “Do drones have a realistic place in a pandemic fight for delivering medical supplies in healthcare systems problems?,” *Chinese Journal of Aeronautics*, vol. 34, no. 2. 2021. doi: 10.1016/j.cja.2020.06.006.

[14] Skydrone Robotics, “Skydrone Robotics conception et fabrication de drones,” Skydrone Robotics. Accessed: Jul. 27, 2023. [Online]. Available: https://skydrone-robotics.com/en/

[15] Victor Riou, “Versatyl : Le drone multi-missions modulaire de l’entreprise française Skydrone Robotics,” Air and Cosmos. Accessed: Dec. 21, 2023. [Online]. Available: https://air-cosmos.com/article/versatyl-le-drone-multi-missions-modulaire-de-l-entreprise-francaise-skydrone-robotics-65387

[16] BPS Kabupaten Nias Selatan, *Kabupaten Nias Selatan Dalam Angka 2023*. Nias: BPS Kabupaten Nias Selatan, 2023.

[17] IAA, *Guidance for Dimensioning of Flight Geography, Contingency Volume and Ground Risk Buffer*. IAA, 2023.

[18] Jarus, *Draft WG-SRM External Consultation: JARUS guidelines on SORA_Annex B_Integrity And Assurance Levels For The Mitigations Used To Reduce The Intrinsic Ground Risk Class*. Jarus, 2022. Accessed: Dec. 21, 2023. [Online]. Available: http://jarus-rpas.org/wp-content/uploads/2023/07/jar_doc_06_jarus_sora_v2.0.pdf

[19] Jarus, *JARUS guidelines on SORA_Annex C_ Strategic Mitigation Collision Risk Assessment. Edition Number 1.0*. Jarus, 2019. Accessed: Dec. 21, 2023. [Online]. Available: http://jarus-rpas.org/wp-content/uploads/2023/07/jar_doc_06_jarus_sora_annex_c_v1.0.pdf

[20] Jarus, *Draft WG-SRM External Consultation: JARUS guidelines on SORA_Annex E_ Integrity and Assurance Levels for the Operational Safety Objectives (OSO)*. Jarus, 2022. Accessed: Dec. 21, 2023. [Online]. Available: http://jarus-rpas.org/wp-content/uploads/2023/07/jar_doc_06_jarus_sora_annex_e_v1.0_.pdf