Good Practice Guide for Airworthiness and Operations of Uncrewed Air Vehicles (UAVs).

A focus on NHS logistics applications.

Revision History

Version 3.3

Embodied comments from ARPAS

Version 3.0

First full release of document incorporating comments from industry experts.

Version 2.7

Final Draft version circulated for comment.

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Introduction

This document has been produced in connection with the EPSRC E-Drone project (https://www.e-drone.org/) and the Solent Future Transport Zone (FTZ) project for which the University of Southampton is leading the Uncrewed Air Vehicle (UAV) work.

The purpose of this document is to capture "lessons learned" from the operational experience of trials that have already been carried out. The E-Drone and FTZ teams wants to use this incremental knowledge to identify, develop and recommend low-risk and economically viable future solutions for the movement of medical products by UAV.

This is a "living" document and as trials proceed, relevant experience will be captured in future releases.

Background

Solent Transport has been granted £29M from the Department for Transport (DfT) to implement innovative future transport solutions associated with personal mobility and logistics.

As part of this project, the university, in partnership with Windracers and Distributed Avionics has undertaken extensive trial flights using a large (350kg) fixed wing platform to demonstrate a logistic link between the Isle of Wight and the mainland. This flight took place in congested airspace and considerable operational experience was gained as a result. The team has also experimented with a wide range of platforms including rotary wing and hybrid VTOL configurations (Figure 1).

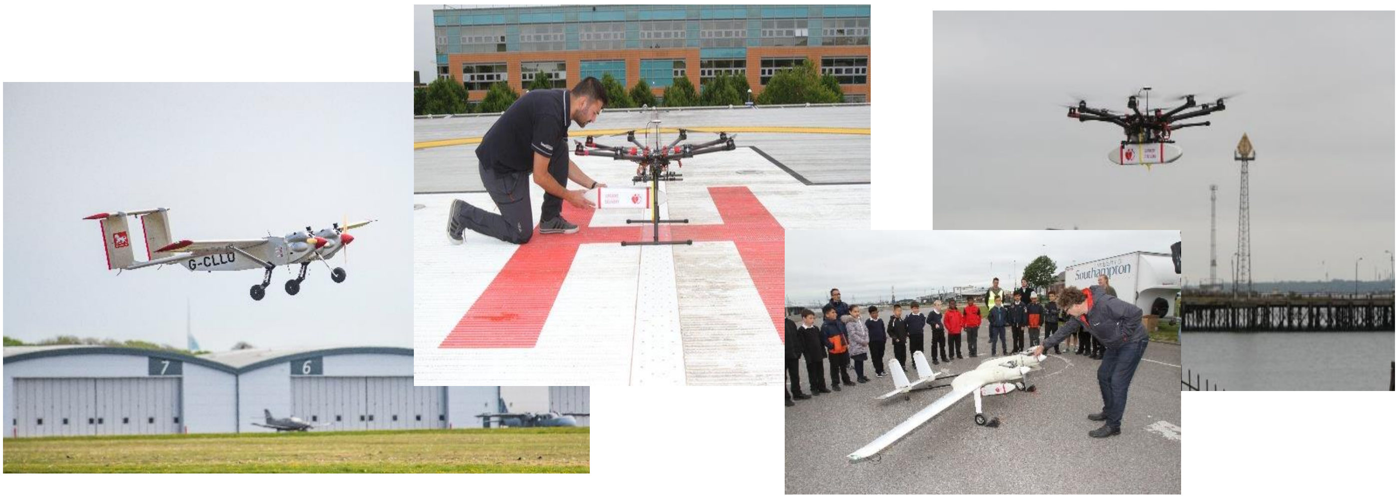

Figure 1 FTZ funded flight trials between Lee on Solent and the Isle of Wight as well as Southampton fixed wing and rotary wing hospital trials

Southampton University is one of the largest operators of drones in the UK and owns around one hundred platforms. These are used extensively both in the UK and internationally. The team has considerable experience of BVLOS operations and was the first non-military organisation in the UK to gain a CAA permission for a >25kg platform in 2012. Since then the team has been granted permits from the CAA for a range of platforms operating BVLOS in complex airspace.

Scope of this Document

The E-Drone and FTZ projects encompass research into a wide range of transport solutions including crewed and autonomous air and ground vehicles. Economic analysis and operational simulation models are being used to determine which solutions provide the right mix of vehicle and systems technology for the various transport challenges of the future. Another key focus, particularly in the E-Drone project is user and public acceptance of such systems as they are introduced into society.

One of these challenges concerns small, high value, time-sensitive consignments. The priority case study selected within this category is associated with NHS logistics. In particular, there is a need for a responsive, low-cost, and environmentally friendly system to transport medicines, blood products, test samples and other similar items between NHS units.

Although analysis and simulation is still ongoing, early results suggest that there is potentially a need for three classes of uncrewed air vehicle platform. The purpose of these projects, and other UK trials, is to prove the necessary endurance, safety, performance and economic criteria for commercial UAV operations targeted at medical logistics.

The classes are as follows[1];

1) **LR**; Long Range/endurance (>50km) platform to connect widely spaced NHS units which do not currently have good logistic connections; for example, Island communities. This class of platform will operate primarily over low risk/ low population density areas.
2) **MR**; Medium Range/endurance (20-50km) VTOL platform to be able to directly connect NHS units and make use of Helipads and other small footprint terminal areas. This class of platform needs to be capable of operating over high risk and high population areas.
3) **SR**; Short Range/ endurance (between 10 and 20 km) VTOL platforms. This class of platform needs to be capable of operating over high risk and high population density areas.

This outline specification document concerns itself primarily with **MR** and **SR** class platforms which will need to operate in high risk areas. As an example, the flights for these might be as follows: MR = Depart Southampton General Hospital helipad with a <20kg multi-rotor carrying blood and vaccine products, transiting on a pre-defined route across the Solent to land at St Mary's Hospital's helipad in Newport Isle of Wight. SR = Depart Southampton General Hospital with a <20kg multi-rotor carrying blood plasma to transit a pre-defined route to Queen Alexandra Hospital in Portsmouth.

Government regulations

Regulations are being continuously refined and formulated as technology is developed and experimentation/ trials are carried out. This document is not intended to repeat or cover the extensive guidelines and requirements given in CAP 722 (Uncrewed Aircraft System Operations in UK Airspace – Guidance) and other related CAA (Civil Aviation Authority) documents but reference is made to certain aspects of these documents. Compliance currently relies heavily on subjective judgement of risks and mitigations. This is why a type certification process might be necessary in the future (but this is complex to develop and expensive to prove compliance).

Clearly, any platform design that intends to operate in the UK needs to meet the CAA criteria and have been granted the necessary permissions before trials are carried out. There is extensive material within the CAA website covering this (https://www.caa.co.uk/consumers/unmanned-aircraft-and-drones/).

There are currently no UAV-specific type certification documents, but these may be developed in the near future. A current priority for the authorities is to develop type certification standards for the emerging Urban Air Mobility (UAM) vehicles that will carry people in urban (high risk) areas and may have highly automated flight controls. Again, this document is not an attempt to define a type certification document. Nevertheless, reference to existing *crewed* aircraft type certification standards and good design practice is made.

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[1] the key difference between these classes is mainly a "time at risk" aspect - The take-off, climb, descent, and landing phases will have very similar risk profiles for all classes (ie likely to be in relatively high population density areas, around a medical facility), whereas the en-route phase (transit) is the key differentiator in terms of overall risk profile (from a ground hazard perspective). The key variant in terms of "time at risk" is the transit, which arguably brings in a greater risk of air-to-air hazard for the longer flights (although this assumption would need to be validated depending on how congested the urban/local airspace is).

The table is essentially a checklist and assessment framework to guide the selection of trial platforms within the FTZ project. It has been put together based on the considerable design, operation and testing experience of the wider FTZ team.

Risk and reliability

Commercial aviation is now a relatively safe mode of transport. For example, the diagram below gives the relative safety record of various modes.

The risk associated with UAV operations is primarily driven by ground risk (ie the danger posed by unintended ground contact) and air collisions (impact with a crewed and other aircraft).

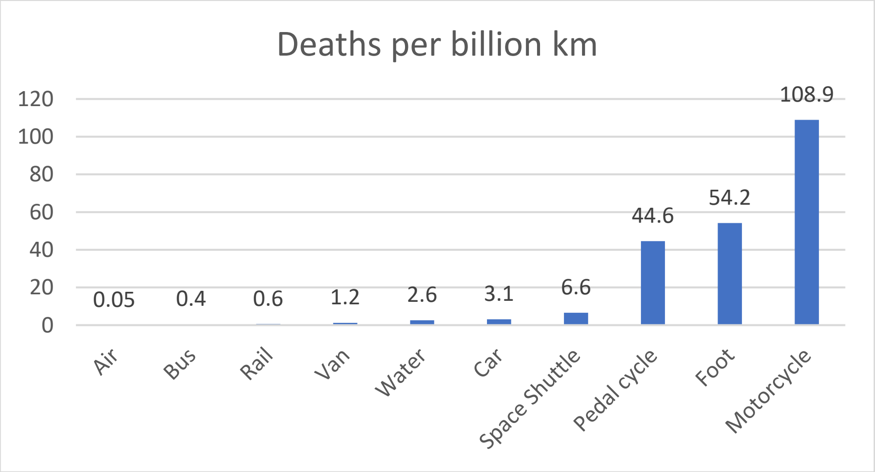

Figure 2 Relative safety record of different modes of transport ("The risks of travel" Archived September 7, 2001, at the Wayback Machine). Note that figures are based on distance travelled and don't account for the actual number of journeys (which is arguably a more appropriate factor for certain modes)

The certification authorities do not currently give an explicit risk target for UAVs although reference is given to acceptable fatal accident rates for certain classes of crewed aircraft. In truth, the figures given are aspirational e.g. a target figure of 10^{-9} fatal accidents per hour of operation is often quoted for large civil airliners. A recent a paper [2] shows that the annual Australian flight hours in high capacity Air Transport Operations (ATO) aircraft was circa one million (2009). This means that a failure rate of, say, 1 in 10^7 flight hours will, on average, result in one such failure every 10 years. Hence, even with high air traffic rates, many years will be needed for accidents or even incidents to accumulate. Therefore, validation of actual systems performance against aspirational performance targets is inherently a major problem.

It has taken many decades for crewed aviation to achieve admirably high comparative levels of safety. The principles on which this safety record is based are given in Appendix A. These principles are associated with expensive and stringent processes which, if applied to UAVs across the board, would possibly lead to unnecessarily high costs. A more nuanced application of the crewed aviation principles is perhaps the outcome we will see over the next few years and this thinking is reflected in the emerging EASA risk-based classification of UAV types[3].

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[2] https://www.researchgate.net/publication/265251293_Target_Level_of_Safety_Measures_in_Air_Transportation_-_Review_Validation_and_Recommendations

[3] https://www.easa.europa.eu/domains/civil-drones-rpas/drones-regulatory-framework-background

Path planning

Considerable research work is underway aimed at developing tools to assist in the identification of acceptably low risk flight paths and policies. The E-Drone funded SEEDPOD project (Simulation Environment for the Evaluation of Drone Policies and Operational Deployment) has created an open-source tool that can automatically find the lowest ground-risk path between two points. This is based on a very sophisticated GIS (Geographic Information System) which includes both static and dynamic population data. This means that it takes into account the change in population density according to both the time of day and day of the week. SEEDPOD already includes categories such as restricted airspace, nature reserves, noise sensitive and prohibited areas. Further developments will include modelling of traffic pattern analysis and the inclusion of weather (wind, precipitation, visibility).

Components

Many small commercial UAVs make extensive use of "hobby-grade" components such as servos, speed controllers, brushless motors, and flight controllers. In general, the manufacturers of these components do not provide details concerning life, reliability and provenance of the relevant supply chain. Hence platform designers using such components must assume that these will unexpectedly fail at any point. NHS delivery trials on the Island of Mull using a "Wingcopter" platform are currently ongoing. This platform was involved in an incident during a flight in September 2020, resulting in the total destruction of the aircraft. Investigation showed that one of the speed controllers failed, leading to a loss of one of the four rotors[4]. For low risk areas this may be acceptable, but for safety critical functions in high risk areas, the use of components of unknown reliability demands the use of high levels of redundancy where the overall system should "degrade gracefully" as components fail and therefore does not result in loss of control.

The members of the FTZ and E-Drone teams have extensive experience in the use and development of flight control systems. This is a particular focus within the FTZ project as there is a desire to de-skill operations and eliminate reliance on highly qualified and experienced manual safety pilots. Hence the platform will largely be under automatic control and, for Beyond Visual Line Of Sight (BVLOS) operations, it will be difficult for a human to use piloting skills to deal with an emergency. Higher levels of true autonomy (Appendix B) is the subject of considerable research effort. It is of note that the biggest single cause of crewed aircraft accidents is now due to human factors issues. There may therefore, be significant relative safety benefits in operating systems with high levels of autonomy on the assumption that the autonomous functions can be assured sufficiently/adequately.

Requirements

The requirements given in this document are essentially aspirational. The FTZ and E-Drone projects are continuously evaluating platforms and "drone" configurations on a world-wide basis. This evaluation activity suggests that there is currently no "ideal" platform in existence and that, at least initially, a sub-optimal solution is inevitable and hence there are associated risks which will need to be identified, mitigated and managed.

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[4] https://assets.publishing.service.gov.uk/media/5fd8ced2e90e071be641bfb3/Wingcopter_178_Heavylift_registration_na_01-21.pdf

The most important requirements are those associated with safety. The platform and related systems will be required to operate intensively BVLOS and therefore likely to rely on autonomous/ automatic flight control.

The FTZ project has a very low appetite for risk because;

a) It will involve realistic trials close to populations and infrastructure

b) A serious incident could imperil research momentum

Over its lifetime, the FTZ project will look to procure various UAV platforms to trial between NHS sites across the Solent. These platforms will have to meet specific safety design criteria defined by the FTZ in order to participate in the project.

Participants in FTZ trials will be required to share all trials data as well as any safety case documents submitted to the CAA.

Platform Airworthiness Guidance

The following guidance is not intended as a definitive guide but should act as a "check-list" of areas that will need to be addressed to meet the future airworthiness for "specific" classes of UAVs (https://www.caa.co.uk/Commercial-industry/Aircraft/Unmanned-aircraft/Small-drones/Flying-in-the-specific-category/).

Systems

Requirement	Rationale	Assessment metric	Comments
Detailed and version-controlled hardware system block diagram	To manage to overall system holistically	Clarity. Has Functional Failure Analysis (and associated Functional Architecture) and FMECA been undertaken?	Principles of ARP4761 followed? Other standards such as DO-178C for software, DO-326A for cyber security for airworthiness
Software system block diagram	To manage software systems	Clarity. Appropriate segregation of safety critical functions	
Robust systems design	Because of need for flight over high risk/ populated areas and infrastructure.	No single point of failure and high level of redundancy for flight critical systems and components	See appendix "D" for example.
Flight control sensors	Need for robustness and redundancy of flight control sensors such as pitot static systems etc	Is there redundancy of sensors? Is icing or water ingress going to cause pitot static systems failure?	
Anomaly detection	Is there a way of detecting inflight or post flight anomalies?	Demonstration	
Detect and avoid	Use of transponders/ strobes/ vision system. Demonstrated reliability and performance in all conditions	Detectability calculations Sense and avoid systems/ capabilities.	Note Clarity is still required (in liaison with the CAA) on the meaning of the regulatory requirement for a DAA system to be "as good as" the human eye

RF noise tolerance	Platform might need to fly in proximity of RF noise sources both external and internal	RF risk analysis and any testing	
High levels of flight automation	Ability to react to anomalies such as excessive turbulence, on-board fault conditions/ comms loss actions such as RTB/ loiter	Demonstration	There is a regulatory requirement to demonstrate assurance of autonomous functionality (at various levels of authority), in order to provide assurance to operators and regulators that the system will react in a predictable and assured manner in all reasonably predictable scenarios.
Automation	Proven ability to operate without skilled safety pilots and use of Geo fencing	Demonstration	Note the need to differentiate between functions which are automated and to what degree of authority - As an example, the CAA is concerned with autonomous/automatic functions related to flight functions (safety and airworthiness), and not with those related to payloads (which is an operational qualification aspect).
C2 communications	Robustness of command and control links	Layered, fault tolerant communications; perhaps LOS RF, LTE, Satcom	
Emergencies	How will significant emergencies and anomalies be managed	Demonstration	Note this pertains to all anticipated issues including other airspace users, wildlife, weather, malicious intent etc
Human factors	Have all known emergency situations been identified rehearsed	Demonstration	
Health monitoring	Live downlink/ health monitoring	List of all systems monitored	Use of non-volatile memory? Recording of CPU utilisation /memory?

	of critical systems on the platform		
Flight test monitoring	Flight information recoding is very useful for incident analysis (see appendix D)	Any provision for "black box" recorders	
Design margins	How close to the performance limits are flight critical components. For example, speed controllers have poor reliability when operated near to their current rating	List and ratings	This applies to control systems including processor capacity and memory
Cooling	Heat is a big factor in the reliability of components	Has sufficient cooling provision been made for components such as speed controllers and batteries? Are temperatures monitored and recorded?	

Aerostructure Design

Requirement	**Rationale**	**Assessment metric**	**Comments**
Design standards	Has the platform been designed to a particular code such as Section S, CS23 or CS25?	Evidence of good structural design practices and the availability, for example, of relevant VN diagrams for various flight modes, and weights. Analysis and testing of critical load cases	
Level of weather tolerance	Cannot afford to suspend services dues to poor weather.	Rain, wind of up to 30 m/s temperatures of -20C +40C Is the system waterproof? Do-160G compliance?	
Ability to address Dangerous Good carriage legislation in relation to cargo hold design, payload collection and delivery	Can the payload be de-coupled from the UAV platform in terms of collection and delivery? Does the payload carriage system conform to EASA crash worthiness testing? Can the payload chamber and the payload be continuously monitored in terms of temperature and vibration during transit?	Reliable, efficient and timely operation. No special ground infrastructure required. No special skilled or DG trained personnel to load/unload	i) If the payload has to be physically attached/removed from the UAV then any ground personnel need to have aviation level DG training. ii) Live monitoring of temperature and vibration is not typically required in the ground transportation of medical cargos but could be mandatory for UAVs
Modularity	Can all major systems and structures be easily interchanged?	Time to change major serviceable items Staff type needed to interchange items (including routine power	

		packs) at origin and destination points.	
Flight ready time from transportation case	Tool free assembly mandatory. Electrical connections built into mechanical connections	Demonstrated time	
Mass and size (structural efficiency)	the lighter and smaller the system the better (safety, handling, regulations, etc.)	MTOW to empty weight ratio	
Benign failure behaviour	List the failure modes of all the key systems such as a propulsion system failure in the event of for example a bird-strike	Evidence of analysis	
Flexibility	Can performance be modified where appropriate; for example, fit larger wings/props for different payload range missions?	Demonstration	
Benign airframe with no intrinsic hazards	Electric propulsion is a major potential hazard. Large diameter propellers can cause injury. Have safeguards been developed and how secure are they?	Safety interlocks or evidence of safety	Interlocks etc must be included in FMECA/single point failure analysis, as could compromise safety in flight.

Performance

Requirement	Rationale	Assessment metric	Comments
High payload mass	Standard NHS cargoes need to be carried. The largest single unit mass would likely be a standard 370mm x 430mm x 330mm (WxDxH) blood transport box (13kg)	>13kg payload weight for MR and SR flights	
High payload volume	UAV platforms should be able to carry standardised NHS packages. It may not be efficient to get the	410 by 360 by 340mm is a common large box size used	

	packaging industry to alter packaging to suit the UAV platform	to carry aseptic medicines under temperature control	
High transit speed	Needs to outperform a van in terms of O-D transit time	>40 m/s	
High range	Larger the better; ability to travel to and from pickup	>50km	Capability to complete a return flight without refuelling/ battery charging desirable
low noise footprint	Transit and VTOL noise emissions	Actual noise propagation footprint in the hover and in cruise.	
VTOL landing and take-off accuracy		CEP (Circular Error Probable)	Include height estimating process and for Baro Altitude setting procedures
Emissions	could exhaust gas be an issue? Needs to produce less emissions than the current land transportation mode	If applicable	
Low vibration	The need for UAV platform providers to prove that their platforms do not cause any adverse effects on medicines/ samples/ blood products during all phases of flight	Measured with sensors for flight test of flight cycle. Vibration levels need to be within specific bounds depending on the cargo	Measurement of primary frequencies from props, resonance etc?
VTOL	Ability to deliver to congested areas and existing helipads	Time to climb to 200 metres and energy used. Declared power reserve for diversion/ hold	

Maintenance

Requirement	Rationale	Assessment metric	Comments
Easy to service and good access to all systems	Reduce cost and service downtime	Time to service	
Pre-flight inspection time	Use of diagnostics and automated health monitoring	Time to check overall system before first flight of the day and subsequent flights	QR codes and RF tags. Electronic BIT covering major systems available/ recorded before flight.
Maintenance schedule	A clear and logical schedule showing replacement criteria for life limited parts and check rules for other parts	Evidence of maintenance schedule and logical life estimates	
Systems reliability and maintenance	Use of and experience of formal safety management systems	Evidence of fault logging and modification history	
Track record of and process for promulgation of system faults and issues such as service bulletins	Has the system been upgraded? Are there known issues? Is there a plan for further upgrades? Have any faults been uncovered?	Evidence	
Parts/interchangeability	All parts should be interchangeable. Should be no "fettling" required (would indicate low design margins).		Parts from crash damaged aircraft never used (airspeederII AAIB report example)
Build standard	Even without using aerospace grade parts, knowing part numbers and where possible batch numbers, helps improve reporting across the UAS sector/identification of eg design weaknesses in a	Electronic record of build standard/ability to query for a part. Ability to interrogate UAV for	

	common part used on multiple platforms. Also need to record software/firmware build standard.	software/firmware build standard.	

Costs

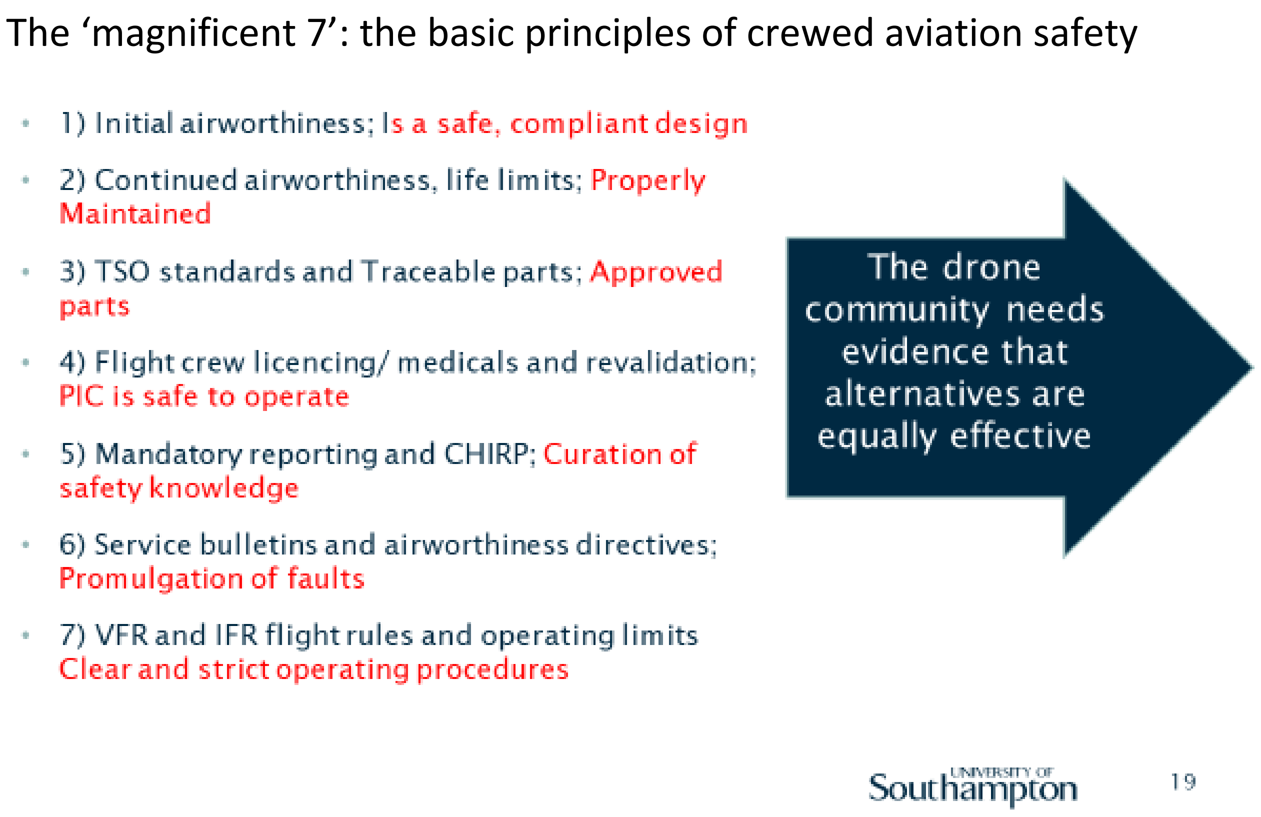
Requirement	Rationale	Assessment metric	Comments
Low Direct operating cost	The platform has to be economic to operate and will be competing with battery powered vans etc	Estimate of direct operating cost and estimate of carriage rate (£/kg/km)	
Good supply of spare parts	What components need to be on-site for routine maintenance and what volumes are needed at any one base station (storage needs etc)	Delivery times for key items, life limited parts and consumables	
Service time	How long does it take to service the platform? Battery change times?	Time estimates	
Turn-around time	To include system safety checks	Time to load and change/ charge batteries/ refuel	

General

Requirement	Rationale	Assessment metric	Comments
Qualifications of team	What qualifications/ relevant experience do key members of the team have such as system designer,	Evidence	accountable managers or asset design authorities who hold responsibility for a key system (software, data processing, voice comms etc) all had to prove why they were competent to hold that position which in most cases was backed up by a recognised qualification, significant experience and/or accreditation

Data management	Need to understand data and cyber security	Evidence	Cyber Essentials, ISO27001. ICO and GDPR
Placards	Use of Placards to inform	Evidence	Refer to recent EASA Special Condition (SC)27 for CS-22 for powered gliders with electric propulsion units . Provides useful reference for design and installation of high voltage stored energy devices, warnings, placards and procedures for reducing the risk to ground and emergency personnel.
Flight planning	Use of operational mission planning/risk assessment	Evidence of use of low risk airspace and ground risk techniques	
Operations	Availability of "hot" back-up systems for ground control failures. Similar "zero points of failure" philosophy for wider systems	Ops handbook	Use of "spare transmitter" (for manual safety pilot flight). Use of fully charged and powered up spare laptop/ ground control system Spare aerials and connectors

Appendix A: Airworthiness



The ‘magnificent 7’: the basic principles of crewed aviation safety

- 1) Initial airworthiness; Is a safe, compliant design
- 2) Continued airworthiness, life limits; Properly Maintained
- 3) TSO standards and Traceable parts; Approved parts
- 4) Flight crew licencing/ medicals and revalidation; PIC is safe to operate
- 5) Mandatory reporting and CHIRP; Curation of safety knowledge
- 6) Service bulletins and airworthiness directives; Promulgation of faults
- 7) VFR and IFR flight rules and operating limits Clear and strict operating procedures

The drone community needs evidence that alternatives are equally effective

Appendix B: Autonomy

Long team research goal; high levels of Autonomy

No **reliance** on C2 links

Full **awareness** of environment

Able to **react** to unplanned events

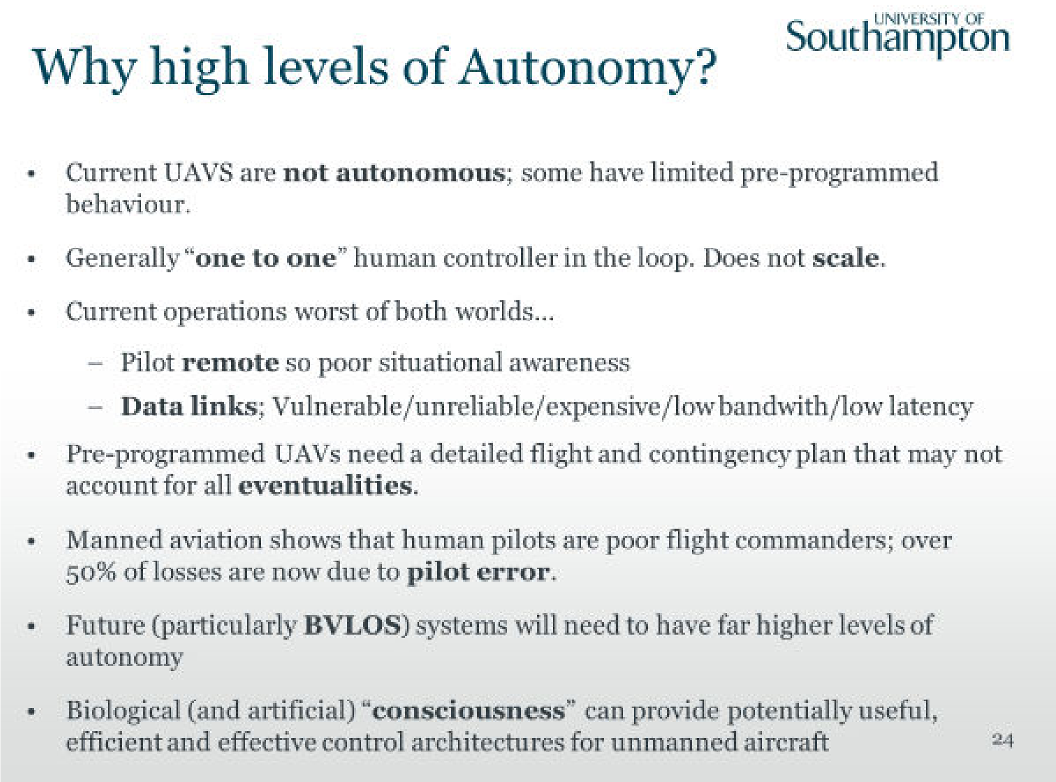
Total **health status** knowledge

Massive array of overlapping, redundant, very high fidelity "**situational awareness**" sensors

No reliance on **GNSS** technologies

Goal driven

No reliance on **human** "minders"

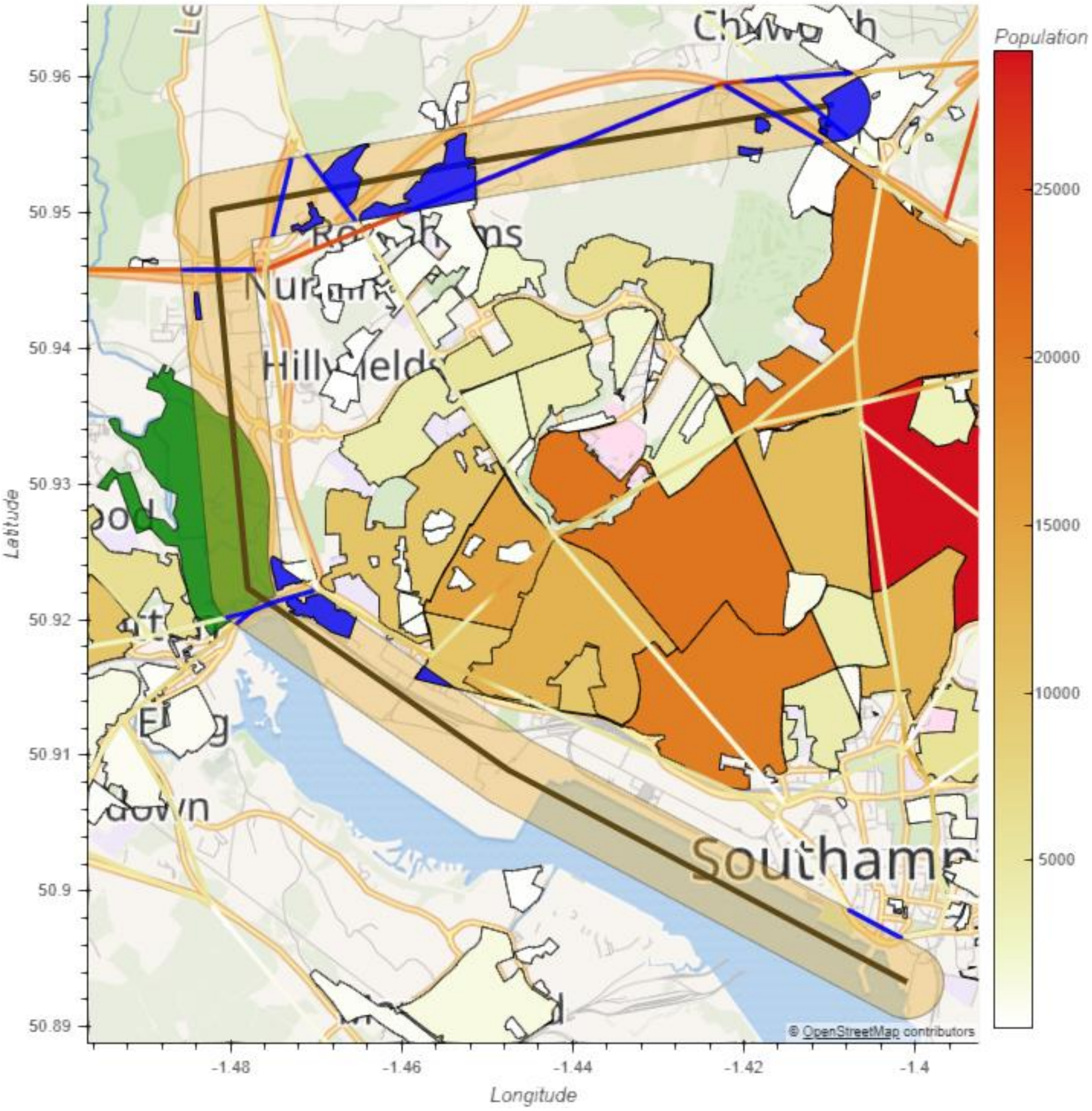


Why high levels of Autonomy?

- Current UAVS are **not autonomous**; some have limited pre-programmed behaviour.
- Generally "**one to one**" human controller in the loop. Does not **scale**.
- Current operations worst of both worlds...
  - Pilot **remote** so poor situational awareness
  - **Data links**; Vulnerable/unreliable/expensive/low bandwith/low latency
- Pre-programmed UAVs need a detailed flight and contingency plan that may not account for all **eventualities**.
- Manned aviation shows that human pilots are poor flight commanders; over 50% of losses are now due to **pilot error**.
- Future (particularly **BVLOS**) systems will need to have far higher levels of autonomy
- Biological (and artificial) "**consciousness**" can provide potentially useful, efficient and effective control architectures for unmanned aircraft

Appendix C: Low risk path planning

SEEDPOD (Simulation Environment for the Evaluation of Drone Policies and Operational Deployment). Open source tool to allow automatic flight path planning for low ground risk (static and dynamic population density)



Appendix D: Flight test monitoring

UOS SPOTTER aircraft was found to have impact damage after test flight. Only after subsequent analysis of integrated flight monitoring system footage was the cause found to be a bird strike (above).

Multiple redundant flight control surfaces which means that control is retained in the event of a servo failure

Appendix E: Payload dimensions and details:

IOW GP Sample Boxes (estimated 350mm x 350mm x 350mm)

Bio-bottle carton (for blue sized bottle) 110mm x 110mm x 185mm (WxDxH)

Swab samples box size is : 230mm x 134mm x134mm carton, containing tube (210mm tall, diam. 120mm) 0.455kg weight
Versapak Small https://www.versapak.co.uk/new-small-insulated-medical-carrier-pathology
Versapak medium https://www.versapak.co.uk/new-medium-insulated-medical-carrier-pathology

Versapak Large https://www.versapak.co.uk/new-large-insulated-medical-carrier-pathology

Small insulated polystyrene carrier (for frozen products)
195mm x 270mm x 310mm (WxDxH)

Large insulated polystyrene carrier (for frozen products): 400mm x 300mm x 290mm (WxDxH)

Postal sample carrier: 130mm x 100mm x 50mm (WxDxH)

NHSBT Blood carriers: 370mm x 430mm x 330mm (WxDxH)

Cooled chemotherapy box: 32cm high, 37 cm wide, 36cm high

Ambient chemotherapy box 41x 36x34cm