

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

**Questions and Answers Session**

Organisation	Subject	Reply
<b>QUESTIONS RAISED BEFORE THE WORKSHOP</b>		
	None	
<b>QUESTIONS RAISED DURING THE WORKSHOP</b>		
	Based on which criteria is an application for a new outside EU DOA accepted/rejected? Is this criteria published?	<p>A policy clarifying this issue will soon be published. Generally speaking, DOA outside EU should have a scope limited to minor changes and minor repairs, as EASA cannot the State of Design for products and changes designed outside EU.</p> <p>The intent is to use article 8.2 of our Commission Regulation (EC) 748/2012 to assess the NAA system and not to approve directly organisation outside the EU but to rely on the system used by the NAA.</p>
	How is the scope of design secured before the application?	<p>Initially, an applicant for Design Organisation Approval should define what is the requested Scope of Work for which it wants to apply. This should be done based on its operational needs and the competences that are available within the organisation.</p> <p>The Agency will check the eligibility criteria and category before accepting any new application.</p> <p>The Scope of Work of the design organisation will be further discussed with the appointed DOA Team Leader during the Investigation process.</p>
	What is the minimum content required by EASA for the Handbook versus the template on EASA website?	<p>EASA has published a template of handbook on the EASA website to guide applicants on the expected content of a DOA handbook.</p> <p>However, the reference remains Part-21 and the handbook provided by the applicant should ensure that all relevant requirements are covered in the handbook. To help achieving this, EASA also shares the "Part-21 Compliance Checklist" which can be filtered depending on the design activity foreseen by the applicant.</p>
	How does EASA manage the timely involvement of DOATLs/experts for the	In case of a new DOA application, the case is allocated to DOA Team Leader

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
	successful investigation of a new DOA/significant change?	within a fixed timeframe, i.a.w. EASA internal procedures. The appointed DOA Team Leader then prepares the investigation plan and determines the need for involvement of Experts. The investigation plan and Expert availability need to be aligned with the DOA implementation planning by the DOA applicant to ensure an efficient review process. The same flow applies for Significant Change applications, except that the DOA Team Leader is already appointed.
	Is there a document (published) identifying the key characteristics of competence?	No, competences should be defined by the design organisation so that it is fit-for-purpose for their Scope of Work.
	It is planned to expand the current pool of EU auditors to non EU states authorities states?	No, no on-going activities on this topic.
	It is planned to create a pool of EASA auditors able to cover several fields (maintenance, design, production, continued airworthiness)?	EASA has been looking into this in the past without being able to reach a satisfying consensus. In the GA Roadmap Project context, there is a Rulemaking Task starting "Part 21 Proportionality" RMT 0689, which will try to tackle this issue.
	Why a major repair cannot be performed by a non-TC/STC holder if the technical capability and design data is in place and available?	As part of NPA 2015-03 on the Level of Involvement, EASA proposed to allow any DOAH having demonstrated its competences and within its scope of approval, to approve Major Repairs to products (see NPA 2015-03 updated par. 21.A.263(c)(5))
	<b><u>Rulemaking Activities Affecting Part 21: Update</u></b>	
<b>Messier-Bugatti-Dowty</b>	The AMC/GM for occurrence reporting will be only published after the entry into force of the Regulation. This create some difficulties to the organisations to comply with the applicable requirements.	In general, AMC and GM should refer to the latest status of a Regulation, the one that has been published. For this reason, there is a need to wait until the Regulation is published, as there can be changes in the last steps of the rulemaking process. Nevertheless, once the Regulation is published, it should not take more than 2 months to publish the associated AMC/GM. The Agency makes every effort to reduce this timeframe to a minimum to have the AMC/GM as soon as possible, but in some cases it is not possible.  The guidance material supporting the implementation of Regulation 376/2014 is not an EASA task, but is being developed by the European Commission. EASA has supported to its drafting but it cannot provide details on the process

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		at its stage in the EC services.
<b>Hybrid Air Vehicles</b>	The new proposal is to introduce the same requirements for SMS in DOA, POA and MOSA. How this situation will be managed, given the fact that both NAAs and EASA will be involved in the approval and oversight? Will there be a single SMS for the 3 approvals?	There will be requirements for this both in Section A and Section B of Part 21. The requirements will be based in the information contained in ICAO Annex 19, and will not be harmonized with the SMS already existing for OPS. The Agency is internally having discussions with the involvement of design, production and maintenance to enable the possibility for companies to use a single SMS Standard for the demonstration of compliance for all their approvals.
<b>?</b>	There seems to be a conflict between EASA requirements and CAA UK requirements in respect to SMS implementation timeframe, as CAA is requiring to have a SMS by 2016.	<p>Post Meeting Note: As a consequence of the recent Agency decision to introduce harmonised SMS requirements jointly in the domains of the initial airworthiness (IAW) and continuing airworthiness (CAW) under a single concept and single rulemaking task, the rulemaking task RMT.0550 has been deleted from the EASA RMP and its content merged with the new rulemaking task RMT.0251 (former MDM.055) to amend the implementing rules for CAW (Commission Regulation (EC) No 1321/2014 ) and the implementing rules for IAW (Commission Regulation (EU) No 748/2012 Annex I – Part-21).</p> <p>In PHASE I RMT.0251 will amend Annex I of Commission Regulation (EC) No 1321/2014 to introduce SMS for Part-M Subpart-G organisations (CAMO) based on ICAO Annex 19 requirements and material already developed within NPA 2013-01(B). In the PHASE II RMT.0251 will amend both the Commission Regulation (EC) No 1321/2014 and Commission Regulation (EU) No 748/2012 (Annex I -Part-21) to introduce in a single step harmonised SMS requirements to cover Part-145 ('MOA') organisations as well as Part-21 Subpart J ('DOA') and Subpart G ('POA') organisations under a common concept based on ICAO Annex 19 requirements.</p>
<b>FL Technics</b>	Some NAAs have issued guidance material for SMS in absence of AMC/GM available from EASA. Can the DOAs use that material in the interim period?	The Agency is aware about the fact that AMC/GM shall be provided to the industry. In absence of that the companies can use AMC/GM published by the NAAs as this material is not mandatory. Nevertheless, the organisations are responsible to check that the material is not in conflict with the requirements

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		of Part 21.
<b>RR Deutschland</b>	Has the implementation of convergence plan in the Agency had any impact in the timeframe for producing and delivering Rulemaking tasks?	As a part of the convergence plan, the rulemaking program was reduced. This was also done, taking into account that the industry complained that in their perception the Agency was creating an excessive amount of rules that were not directly related to safety. As a result of convergence, the rulemaking officers currently work closer to the PCMs and are more in contact with the field activities.
	<u><b>DOA Terms of Approval (ToA)</b></u>	
<b>Air France</b>	The proposal from the Agency is changing the philosophy of the DOA concept. This can create a problem for a TC holder that will prevent him to obtain a new TC as the new type cannot be in the ToA. The concept of rating is related to a Part 145 organisation but not to a DOA. The risk involved in the proposal is that a project developed by a DOA can be stopped due to part of the activity not being covered in the ToA. The CVEs will also be prompt not to sign if they have a doubt about the design being covered by the areas mentioned in the ToA. This is an auto limitation system	The new proposal does not change the philosophy of the DOA concept, but simply presents the current system in a more standardized and structured way.  A TCH need to have all the areas. An application for a new type can be done before the new type is included in the ToA. The same concept is applicable to STC applicants. Every time there is a need to extent the scope there is a need to apply for a significant change. This is also the same situation today. The proposal only presents the information in a different way. Also, for CVEs the new ToA will be suited, as it will show more clearly the approved scope of the design organisation.
<b>Airbus</b>	Was the proposal for a new way to manage ToA communicated to the industry to get comments, feedback, counterproposals, etc.?	The proposal does not involve any change in Part 21. It is an internal tool to better manage the ToA. There is not any associated change in the regulation. On the contrary, the proposal only presents the information in another way. Hence it is not foreseen to consult formally the industry on this proposal. Information will be provided by each DOATL on due time to all DOAs.
<b>Airbus</b>	The list of disciplines in the ToA will be used to measure the competence of the DOAs. Does EASA have a tool or a recommended practice to measure competence?	EASA does not assess the competences of a DOA. The DOA itself assesses the competence of their staff. The nomination of the staff of the DOA should be based on the assessment of competence, and this process is a DOA process. The Agency only checks that the process works appropriately, in many cases

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
		by means of sampling. After that the Agency will measure the performance of the DOA, and this will be necessary to establish the LOI of the Agency.
?	The proposal is potentially putting a limitation on what the DOAs are doing today. This is a concern for us. It is suggested that the Agency reconsider to have some consultation with the industry on this.	All the ToA will be updated progressively and discussions between each TL and companies on the updated ToA will take place as of beginning of 2016. This discussion will be individually based, given the fact that the ToA are not homogeneous. They are no comparable, given the fact that the information contained inside is different, and was prepared at different timeframes. Also, the update of the ToA cannot be done publically but needs to be done by means of individual meetings. In case a DOA does not agree with the output, there is a possibility to escalate the issue within EASA. The Agency does not need to consult the industry each time that a form is changed.
<b>Lufthansa Technik</b>	It is understood that some systematic is necessary for implementing LOI, but the proposal seems to be too detailed. The consequence is that EASA will end up with a lot of significant changes. We suggest to put this information in the Handbook to avoid additional work for the TLs. Apparently EASA discussed this proposal with the industry. Were airlines involved? We are not TC holders and we have other priorities.	The level of detail in the ToA needs to be balanced, so that it is representative of the type of projects that are within the design organisation's competence.  Consequently, there should not be any need for a DOA holder to apply for a Significant Change to its ToA for new projects, unless it is in a new area for which the DOA has not yet demonstrated its competence to the Agency.
	<b><u>Flight Test Organisation Manual and Flights Categorisation iaw Part 21 Appendix XII</u></b>	
<b>RR Deutschland</b>	As an engine TC holder we have customers outside the EU who do flight tests. Do we have to have a DTO for that activity?	If such flight testing is performed on behalf of the engine TC holder's design organisation (e.g. in order to demonstrate compliance with airworthiness requirements) the DO is responsible to demonstrate its compliance with 21.A.243(a) which can be achieved by an agreement to make use of the FTOM established by the actual operator of the aircraft, provided the DO has ensured that this FTOM meets the 21.A.243(a) requirements.
<b>Specialist Aviation Services</b>	We have to transfer our existing procedures to flight test from our Handbook to a FTOM in 2 months. There should be more time for this activity.	FTOM content can remain in the Handbook or be transferred to a separate document which needs to be cross-referred in the Handbook.

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
<b>Ltd.</b>		
<b>Specialist Aviation Services Ltd.</b>	CAA UK did not have a specific flight test rating. For many years flight testing activities in our organization were done by former army members approved by CAA that did not have any instrument rating.	All UK flight test pilots should have been recognised by now through grandfathering in agreement with FCL 820. The lack of IR for some of the flight test pilots is not a problem, as it can be included in the license as a limitation during the grandfathering being the pilot granted with a license anyway.
<b>Airbus</b>	Is compliance with FTOM requirements subject to a significant change?	If the organisation is already doing flight testing activities, it is not a significant change. If the organisation wants to introduce this activity for the first time, or to subcontract it, then it becomes a significant change.
<b>?</b>	We currently do flight testing. Will the FTOM allow us to fly 10% above Vn without the involvement of the TC holder?	The answer is yes in case the pilot has a CAT 1 and is able to assess the safety of the flight. For this, the intended activity needs to be justified and recorded in the flight conditions. It is a matter of competence of the pilot but it also involves the complete evaluation of the conditions of the flight to be performed, the safety aspects and the conditions established. The decision to carry out a flight test is not a decision of the pilot. It is up to the DOA to establish the flight conditions and have them approved, or approve them using their privileges. Then, the pilot carries out the flight in agreement with flight conditions.
<b>Thales Avionics</b>	What is the status on the ANPA for the future of leading flight test engineer?	The topic is still under discussion. EASA is not in favour of a Crew License for Lead Flight Test Engineers.
	<u>Input from Side Meeting of Group 4: Rotorcraft Community</u>	
<b>Specialist Aviation Services Ltd.</b>	When it comes to the installation of medical equipment in rotorcraft (incubators, oxygen, etc.), the medical equipment requirements are more stringent than CSs. Would it be possible to take credit of that in the certification of the installation?	Will be addressed in RMT.0018 & RMT.0571.  Until the RMT has been completed, the issue can be addressed through a CRI - to be proposed by the DOA.

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
<b>Specialist Aviation Services Ltd.</b>	I subscribe that FAA website is more user friendly than EASA website	Noted.
<b>FL Technics</b>	The classification presented for parts without Form 1 is interesting and may be helpful for DOAs. Decals are a good example of this case. In many cases, decals are produced and the DOA performs reverse engineering to approve them. Are decals group II or group III?	The presented classification is a proposal in RMT.0018 & RMT.0571. It does not reflect the current regulation.
	<u><b>Input from Side Meeting of Group 1: Airlines Community</b></u>	
<b>Airbus</b>	The ASD DOA think tank is currently writing a standard on classification of repairs. Any input from the airlines community is welcomed.	Acknowledged
	<u><b>Input from Side Meeting of Group 2a: General Aviation Community (including ECHs)</b></u>	
<b>FL Technics</b>	Apparently EASA request a STC for the operation of an aircraft with the seats removed. What is the rational for that?	A normal passenger aircraft that is intended for commercial passenger carrying operations will need to have a limitation to zero passengers when no seats are installed. At the same time a cabin interior with no seats is an unusual and novel design that may also require the issuance of a CRI.  If there is a need to ferry fly an aircraft with an empty cabin from point A to B the "normal" way to do so is a permit to fly. EASA would then only approve the flight conditions if this is not in the scope of approval of the DOA.
	<u><b>Input from Side Meeting of Group 3: Small Organisations Community (STC holders)</b></u>	
<b>?</b>	Why was the working group on classification of changes to cabin disbanded?	EASA remains convinced of the need for improved guidance on Cabin Safety change classification. Unfortunately, the working group has not met for a while now due to EASA workload issues. The work to date has highlighted the

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		difficulty of formulating workable guidance material to cover the highly variable nature of Cabin Safety changes without risk of needlessly restricting design organisation flexibility. Notwithstanding this, EASA plans to formulate and issue for comment a Certification Memo on the subject before the next DOA/CT workshop.
	<u>Input from Side Meeting of Group 5: Aerospace and Defence Industries Association of Europe (ASD)</u>	
<b>FL Technics</b>	Airlines already got a procedure for the approval of minor-minor changes and deviation. If your proposal is introduced in Part 21, the airlines will need to update the procedures which are working pretty well. Is it necessary to modify Part 21?	The Agency is supportive of the ASD initiative to develop industry standards - and monitoring their compliance with Part-21. However, the Agency will not impose the standard (once published) on all DOA's, and it will not trigger any change to the applicable regulations. Ultimately, each DOA is responsible for its own procedures.
<b>Specialist Aviation Services Ltd.</b>	It is true that there are already procedures for concessions in most of the DOAs. The risk of the proposal is that the Part 21 is changed without changing other requirements like Part M and Part 145. If that is done, the problem will move to the next layer. In example, if we do not mark part, the MOA will have problems	The Agency is supportive of the ASD initiative to develop industry standards - and monitoring their compliance with Part-21. However, the Agency will not impose the standard (once published) on all DOA's, and it will not trigger any change to the applicable regulations. Ultimately, each DOA is responsible for its own procedures.
<b>Hybrid Air Vehicles</b>	Any guidance on part marking is welcomed. In respect to concessions, for those cases where there is no effect in compliance, if the proposal is to start making justifications, then this is seen as a burden	Justification for concessions is always necessary as per the current regulation.
<b>British Airways</b>	For editorial changes to repairs with no additional demonstration of compliance, there is no need to have a signature of a CVE. Is it the same case for repairs covered by existing ones?	If a damage is covered by an existing (approved) Repair design, this may be (re-)used , as long as the conditions & limitations of the existing Repair design are respected.
<b>Thales Avionics</b>	Having marking requirements in the case of ETSO is quite restrictive. Will it be possible in the future to use electronic marking (e.g. in a flash memory)? For traceability purposes, electronic marking is adequate	Main ETSO standard(s) (hence 'ETSO' status) has(ve) to be visible on the physical label, in order for production, operation and maintenance to have a direct reading of this information.



**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
?	The definition of FAA of minor is a good definition for minor-minor. If EASA is going to provide guidance on minor-minor classification, I would appreciate that this is harmonized with FAA. FAA's AC 43 has a lot of examples. If those could be made valid by CS-STAN, many problems could be avoided.	CS-STAN is not intended to be extended. The target of this CS is the general aviation activities. It is not possible to compare it with FAA minor alterations, because the minor alteration of the FAA is a concept that is different from the EASA concept of minor change. A minor change is a change to a TC, while an alteration refers to a given aircraft. In respect to minor-minor classification, the Agency would be happy to receive a common proposal from the industry, but there would be a need to have a consensus first in order for the Agency to launch a rulemaking activity.
Emirates	We use design deviation authorizations/concessions for individual MSN, We need to continue discussion on this topic.	The Agency is supportive of the ASD initiative to develop industry standards - and monitoring their compliance with Part-21. However, the Agency will not impose the standard (once published) on all DOA's, and it will not trigger any change to the applicable regulations. Ultimately, each DOA is responsible for its own procedures.
	<u>Industry's Initiative: AeroSpace and Defence Industries Association of Europe (ASD) Update</u>	
Airbus	The SMS concept paper is interesting and can be a common standard without the need to have an approval, which could be also valid for the US system and other systems	Regarding your proposal to have an international standard for SMS, you should take into account that in Europe we have the DOA concept, while this is not the case in other systems. Reaching an agreement with other authorities on having a common standard could be difficult and could delay the finalisation of the standard.
	<u>Level of Involvement + Risk Based Oversight –Evaluation of DOA Performance</u>	
	What is the current status of the WI related to the DOA oversight?	EASA is currently working on the revision of the WI based among others on the comments we have received from Industry. With the support from Industry we are confident that we will achieve a very relevant result especially when it comes to the revision of KPIs and calculations.
Anjou	What is EASA's position regarding crediting those organisations that are Certificated European in Lol? What is your position about crediting those	EASA measurement of performance approach is based on Part 21 and at the moment we don't consider any other approach. Perhaps in the future this

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
<b>Aeronautique</b>	organisations that are certified European 9100 in relation to risk based performance in Lol? Is there some special position considered for those organisations?	could be a possibility but currently this option has not been considered.  The TC holders or DOAs will propose the Lol first. Later on EASA will have the option to deviate.
<b>RR Deutschland</b>	Would this be a transparent process from the point of view of the justification?	EASA is aware that some transparency is important. There will be a need to work in the communication which will represent a big change in the management process. Also a common culture will be further developed where documentation will be an important aspect. Even though this is not a new aspect for some stakeholders some others will need to adapt to comply with these new requirements. Furthermore, we will also describe how to make best use of the Lol. Therefore Lol description and record will be the key in the future. We will have to base our technical involvement maybe on the scoreboard and in case of deviation EASA will have to provide justification to substantiate it. We are aware that any frozen situation related to Lol will lead to failure therefore this is considered a living process. EASA expectancy is that Lol will bring more transparency in the process compared to the current situation.
<b>Airbus</b>	As this process is a new concept, I would like to know if EASA has conducted some pilot projects to evaluate how the performance tool will work.	The tool has been used for smaller organisations for the past 18 months. As an outcome of these pilot projects, the Work Instruction (WI) has been amended. Furthermore, the WI is considered to be a living document into which additional items can be incorporated when considered necessary. At present the work instruction is being updated on a regular basis to account for the changes to the process and to account for comments received from internal and external stakeholders. The approach is for DOATL to analyse data each year to determine the level of oversight for the next year. Data taken from dashboard will be contributing to the DOATL's analysis on what level of oversight needs to be performed each year. Today, experts are already providing constant feedback to DOATL based on their practical experience in order to refine oversight upon completion of the project. Only if an issue has been identified EASA will perform a more detailed 'a posteriori' check. These checks are different from continuous checks. We do not expect an increased permanent oversight. It is a total approach with two legs: organisation and

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		product.
<b>Airbus</b>	<p>The quality of the data EASA get together as well as the amount of correct data is critical for getting a good analysis. It is a kind of statistical approach so you need a robust data to get the right picture of what you do. There is a big worry that using all these values to a certain extend for the Lol (which is an important aspect of the performance of DOA) needs the right understanding and statistical approach.</p> <p>Furthermore it needs also to ensure the transfer of the intelligence in the tool. In order to do so, EASA will need to include the raw principles of DOA team leaders as well as their knowledge to avoid having this knowledge disappeared when the DOA team leader (leaving gathered data unassessed) leaves and/or is replaced.</p>	<p>Part of the data are provided by the DOAH, hence the DOAH is responsible to provide the data with a high level of quality. The remaining of the data come from EASA internal databases whose quality is guaranteed by EASA internal procedures (findings, feedback from PCMs/Experts, scope, etc).</p> <p>The tool is only aiming at supporting the analysis of the DOA Team. A disclaimer has been added to the tool, to explicitly state that it forms only part of the 'picture' and requires analysis by the DOA Team Leader.</p>
<b>RR Deutschland</b>	<p>It appears from the presentation that there are basically two options: either to change Part 21 or to raise a CM. We are going into a new path here using Certification Memos for new subjects and I am worried about that.</p>	<p>Certification memos are useful tool if used properly and carefully. We are working with Industry and with the Lol Steering Committee in which industry is represented. Certification Memos are considered soft law compared to GM for regulations. : today we have two scenarios: Certifications memos under Agency responsibility (can be modified rapidly) and amendments of Part 21 (regulatory) that require a lengthy process in case of a revision. The purpose is not to close doors for a long period before we are sure that what we have worked on is to our satisfaction. Furthermore, we are aware that the CM raises certain risks but is an open compound process. In addition to this, it should be highlight that Lol is an EASA process but which has been heavily discussed/developed with Industry. We have to start from a simple approach and from there develop as we gain experience.</p>
<b>Dassault Aviation</b>	<p>The US is also implementing a kind of scoreboard for ODA offering the applicant the opportunity to assess the performance of the FAA. To which extend EASA is prepared to access its own performance?</p>	<p>EASA already implemented a 'stakeholder feedback' survey which is the means for the applicant to score EASA's performance [ <a href="http://easa.europa.eu/stakeholder-feedback">http://easa.europa.eu/stakeholder-feedback</a> ].</p> <p>The Agency values this feedback very highly, and hopes that all DOA's that receive the invitation to provide their feedback take the (short) time needed</p>

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		to fill in the questionnaire.
<b>UAE General Civil Aviation Authority</b>	From the perspective of non-EU design organisations (17 applications currently). These organisations have design organisation approvals from the local authorities based on EASA design organisation approval and subject to oversight by local authorities. In your dashboard how this would be considered?	<p>See previous question.</p> <p>A policy clarifying this issue will soon be published. Generally speaking, DOA outside EU should have a scope limited to minor changes and minor repairs, as EASA cannot the State of Design for products and changes designed outside EU.</p> <p>The intent is to use article 8.2 of our Commission Regulation (EC) 748/2012 to assess the NAA system and not to approve directly organisation outside the EU but to rely on the system used by the NAA.</p> <p>Consequently, we do not intend to use data coming from an outside EU NAA to feed the EASA DOA dashboard.</p>
<b>Thales Avionics</b>	There is a risk that when you implement the methodology there will be no change to the Level of Involvement. If we look at the global methodology more criteria are set to implement Lol resulting in more involvement. Granularity should be adapted to allow difference Lol dependent on area of discipline. Privileges should be provided in return. This means DOA should also be possible for ETSO.	This is not the case. We have a certification process with mandatory steps including a much more technical management involvement in order to provide guidance on what the teams need to do. Our expectation is that there will be a change and that we have to implement this change. The expert/PCM feedback is important to adjust our system. Today it is difficult to know the Lol agreed. With this new process the Lol will be more visible, more transparent and formally documented. The DOA performance assessment at the level of the Panel of Experts only is not sufficient, this is why the concept of “disciplines areas” is very important.
	From the perspective of ETSO applicants, if you want to provide incentive the ETSO to go to DOA EASA should provide privileges. Today, there is no official privilege for DOA holders and currently there is no DOA for ETSO (non mandatory DOA) but if the organisations wishes to go to a higher level (at the DOA) they need privileges such as to sign (to deliver ETSO authorisation) like an STC non-significant.	Today if organisations need to go for an ETSO authorisations an AP-DOA is needed. There is currently a project ongoing to allow a full DOA also to design ETSOA. But there is a need to adapt the procedures especially in term of classification of changes for such DOA. For more complex ETSO equipment EASA is considering to require a DOA which would then also entail privileges but not the privilege to sign ETSOA themselves. So we need a dedicated

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		procedure for DOA that want to go for ETSO authorisations.
	<u>Operational Suitability Data (OSD)</u>	
<b>Lufthansa Technik</b>	How can we apply for OSD approval when no DOA OSD procedure is available? We have no legal basis to do it.	It is correct that if you do not have OSD in your term of approval you cannot apply for OSD. Therefore we need to work in anticipation as regulatory framework is not frozen yet. To do so we have developed and distributed to the PCMs an interim policy defining the intermediate steps in order to apply as consistently as possible the OSD process.
<b>Lufthansa Technik</b>	Having 2 application forms for a STC (type design change and OSD change) is confusing. Why do you need 2 applications?	We are working in order to combine both applications into one. In the future, we will only have one application for Design and OSD. One idea could be but this needs to be further considered than when there is a mayor major Design change associated with a minor OSD change you could probably have one application for the change as a whole with the statement that the OSD change is included but is minor. We need to see how will this all fit in the form.
<b>Dassault Aviation</b>	Can you re-clarify activities versus target the dates especially next December 2016 for STC vs any change of OSD to be implemented or needed between December 2015 and 2016?. Is it applicable for the TC holder only? When is OSD applicable to the Type design?	The rule has two deadlines The 18/12/2015 is the date where TC holders have to comply with OSD requirements. The deadline of 2016 applies to changes to OSD. What has not changed in Part 21 is the provision for eligibility for DOA doing major changes or STCs. The only exclusion we have made is for TC holders where EASA was has giving 2 years to comply with OSD. As a consequence, TC holders doing major changes next year can only dto that if their DOA covers OSD aspects. Also as a remark Industry needs to consider OSD changes only in cases when there is an OSD in the TCDS in the first place. Therefore if there is no grandfather OSD or no catch-up OSD (of aircraft with old aircraft designs) this is not applicable.
<b>Dassault Aviation</b>	Can you explain what is been done together with the FAA for streamlining the issuance of an MMEL so that it can be used by US authorities. For Industry it is key to deliver an MMEL in due time to our US customers.	Today the OSD is not covered by the bilateral agreement with the FAA therefore some creativity is needed and there is a need to anticipate and to develop data. Also under the COB there is a new group dealing with the implementation of OSD and specially solving critical issues in particular linked with MMEL.

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
<b>Dassault Aviation</b>	When we have a major change together with a minor one (OSD embedded element) it is been understood that we will need to apply via the 2 Forms. For this case would it possible to use one single document to lightener the administrative tasks?	We are working in order to combine both applications into one. In the future, we will only have one application for Design and OSD. One idea could be but this needs to be further considered than when there is a mayor major Design change associated with a minor OSD change you could probably have one application for the change as a whole with the statement that the OSD change is included but is minor. We need to see how will this all fit in the form.
<b>Virgin Atlantic Airways</b>	OSD classification is outside 21.A.91. If the type design change is minor then there is no OSD. In EASA's presentation they were mentioned cases where there was a minor type design change with an associated minor OSD change. So can you please further develop the idea?	OSD is considered part of the Type Certificate so it has to be included in determining the classification of a change according to 21.A.91. Also, we consider that a change in the TC has to be classified minor. Now, in order to allow DOAs to use their privileges for approving minor changes the classification needs to be done separately. A Design change can be classified separately as well as from the change to the OSD. However, in the end of course legally if the Design aspect change is major and the OSD change is minor the whole change will be major. In the future, should the applicant inform the Agency that the associated OSD change is minor, the later will then establish using the Lol whether there will be or not a need to review the OSD part. The classification as minor of the OSD part of the change will be used to determine the Agency's LOI.
<b>Virgin Atlantic Airways</b>	For those Design organisations having only minor changes/repairs, is there any point to apply for OSD in the terms of approval?	Our guidance material will specify that in principle minor design changes have no effect on OSD except for a few cases for MMEL. So in general there will be no need for you to extend your DOA scope to include OSD. On a case a case by case bases if the Agency sees that a minor change has been approved by a DOA that would have had an MMEL change then you might be required to retrospectively to show compliance. It will be advisable to discuss this with the DOA team leader to insure what needs to be done in respect to OSD.
<b>?</b>	How does an STC applicant gains access to the TC holder data in order to make the evaluation as to whether a change is necessary or not in the OSD field?	TC holder has a legal obligation to provide data to the operators office lead and to those who are required to comply with the OSD data such as training organisations doing type rating training.  STC applicants may get the data through their contacts with the operator.

**Part 21 DOA Implementation and  
 Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
	<u>Input from Side Meeting of Group 6: DOA'S OUTSIDE EU</u>	
<b>Air France</b>	For DOA applicants outside Europe there are not fees foreseen for travel and subsistence. This is not the case for an EU applicant and therefore this difference of treatment is not fair.	When EASA travels outside Europe we invoice the costs which is not the case when we travel inside the EU. It is a fair treatment as we have to work with our own EU Fees and Charges regulation. The Fees and Charges regulation has two schemes inside EU and outside EU. In the inside EU schemes, travel and subsistence are included in the Flat fees. It is a fair treatment for the EU industry as we don't charge on top of the flat fee travel and subsistence expenses.
	<u>International cooperation</u>	
<b>RR Deutschland</b>	From the BASAs perspective we talk about non retained validation items for major changes. Is the DOA granted to the DOA holders covering validation items for non-retained aspects? Can we use the privileges? Are we obliged to comply with Part 21 for non-retained validation items? i.e. CVE tasks	<p>Yes, we do not see on what basis the FAA could challenge the qualification process of a CVE, even in the context of a VI.</p> <p>Of course, we do not say that that the FAA is forced to accept a document checked by a CVE without further verification. But as far as we know, the BASA is not challenging our Part 21 on these aspects (CVE, ISM and use of DOA privileges).</p> <p>The TIP, Appendix C, paragraph 8.8 says that the CA approves against the VA Certification Basis. As the FAA accepts our DOA system there should be no doubt that a statement from the DOA is acceptable.</p>
<b>Dassault Aviation</b>	There are foreign authorities asking for the validation of our DOA. We should avoid in the Design area what the Industry suffer in the Maintenance area where it was require to cover our walls with foreign MOA certificates.	<p>Any state has full sovereignty when deciding what rules are applicable to the aircraft flying in, out or within its national airspace.</p> <p>That being said, EASA and the European Commission are actively seeking cooperation with third-party authorities, in order to support the European industry and to reduce administrative burden.</p> <p>To date 3 Bilateral Agreements and 43 Working Arrangements (plus several dozens of Memorandum of Understanding) are in place.</p>

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
<b>Dassault Aviation</b>	What is the scope of the Chinese Bilateral? We have a concern regarding the spare parts business. Currently, when we have to provide spare parts to China we need to have a Maintenance organisation/production organisation that has the Chinese Certificate. We expect that with the bilateral the additional Chinese recognition will not be needed anymore.	It is intended to accept each other's production system under the envisaged Chinese Bilateral.
<b>Dassault Aviation</b>	Regarding the scope of the next TIP revision with the US, the MRB validation is apparently not included in the next TIP revision despite COB group is working on the issue. Furthermore, when can we expect the TIP Rev. 5 to fully enter into force, i.e. when can we expect the amendment of the Annex to be effective?	<p>When the BASA with the US was adopted, the Council specified the modalities for the amendment of the BASA or its annexes. In this case, we need to change the text of the annex and therefore before the Commission can formally adopt this change in the BOB meeting, with the FAA, the Council needs to be consulted. This process has been initiated and it takes several weeks. As soon as the process is completed on EU side, the decision should be adopted by the BOB, by written procedure and enter into force upon its adoption/publication.</p> <p>The US COB task definition group has been tasked to propose a revision to the TIP by February 2016. This proposal, if approved by the COB at its subsequent meeting, will be issued as part of revision 6 to the TIP.</p>
	<b><u>Maintenance Review Board (MRB) Process under DOA</u></b>	
<b>Airbus</b>	We have been instructed to remove the Lol concept of the pilot project for MRB. What is the reason for this request?	<p>This request was driven by the fact that the CT-directorate is working on Lol rules and guidance (common approach), what we saw in the procedures from applicant was not in line with the NPA. Need to work with industry to have common understanding.</p> <p>Lol will be implemented at a certain stage. When we see the level of maturity of Lol in itself, today including Lol for MRB it can be considered too ambitious. Also had difficulties to sell MRB/DOA/Lol into US system initially, now we go beyond (eg mutual acceptance).</p>
<b>Dassault</b>	Acceptance of MRB approved by EASA by FAA without further involvement is a	Noted.



**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
<b>Aviation</b>	big step. Hopefully EASA could progress on the same lines with MMEL	
	<u><b>Regulation 376/2014 for Occurrence Reporting: Impact on DOAs and DOATLs Activity</b></u>	
	What will be the impact on DOAs and DOA Team Leader's activity?	<p>EASA worked with the Commission to align Regulation 376/2014 with existing Part 21 reporting requirements.</p> <p>In practice, Regulation 376/2014 does not change the continuing airworthiness process, where occurrence reporting and analysis is fundamental part of, but brings more prescriptive requirements in terms of deadlines and reporting format. It also formalises the internal reporting and the establishment of Just Culture in the organisation.</p> <p>Regarding the impact on the DOA TL activity, in principle the surveillance activity is based on Part-21. Given the coherence of Part-21 and Regulation 376/2014, the oversight by the DOATL will cover part of 376/2014, but not necessarily the full extent of that regulation.</p> <p>In any case, DOA should have a single reporting process giving compliance with both sets of requirements.</p>
<b>?</b>	It has been mentioned that the performance of the DOA will use as a criteria the number of AD issued. Is it not in contradiction with the principle of Just Culture?	This is one of the KPI that has been considered, but it is already proposed to be removed.
<b>Baines Simmons</b>	What is impact of the new regulation 376/2014 on Part 21.A.3. and AMC 20-8?	Regulation 376/2014 is applicable to all organisations, including DOAs, established in MS territory. This means that those DOA will have to ensure compliance with requirements in this regulation in addition to those already applicable in Part-21. However, Regulation 376/2014 does not change the continuing airworthiness process, where occurrence reporting and analysis is fundamental part of, but brings more prescriptive requirements in terms of deadlines and reporting format. It also formalises the internal reporting and the establishment of Just Culture in the organisation.

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		<p>In any case, DOA should have a single reporting process giving compliance with both sets of requirements.</p> <p>Regarding the AMC 20-8, while its content is not reviewed, it remains a valid reference on the implementation of the reporting network supporting the Continuing Airworthiness process of the Type Design. It provides the principles of the reporting between organisations and a reference list of occurrences reportable to the Design Approval Holder and to the competent authority, especially for foreign organisations.</p>
<b>FL Technics</b>	If you work for authorities worldwide, how will you compile information and analyse it? How would you publish it to the rest of the EU members States? In which format? Is it reactive or proactive? Would we need to go on the website to find what incidences we had?	<p>Regulation 376/2014 provides for the access to the European Central repository to collect data and conduct analysis. The Agency is currently developing its own Safety Risk Management process which intends to support the European Plan for Aviation Safety (EPAS, former EASp). Within this process there are several analysis and safety publication activities that count on the liaison with external stakeholders, such as the Network of Analysts. This partnership will help the Agency to ensure that the outputs (analyses or safety publications) are consistent and bring relevant messages to the aviation community.</p>
<b>FL Technics</b>	How does EASA intend to publish the safety information? Will it be in a proactive or reactive way?	<p>The Agency is currently developing its own Safety Risk Management process which intends to support the European Plan for Aviation Safety (EPAS, former EASp). Within this process several safety publications are developed like the Annual Safety Review and the identification of the most relevant safety issues in the different aviation domains (Risk Portfolios).</p> <p>Based on the analysis of the Safety Issues pointed out by the ASR and the Safety Risks portfolio, the Agency can decide to raise awareness of particular safety issues and use regulatory or safety promotion tools. This can also lead to the publication of Airworthiness Directives and Safety Information Bulletins by the Agency. These documents mandates the correction of unsafe conditions and raise awareness of potential safety issues, respectively.</p> <p>The collection and analysis of occurrences provides for proactive safety to</p>

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
		complement the reactive approach to accidents.
<b>Thales Avionics</b>	Can you clarify when the time starts to count in respect to the 72 hours for reporting?	The starting point is the moment in which you detect the potential unsafe condition.
	<u>The EASA GATEWAY project</u>	
?	We currently do many activities under provisions of 2.A.2, meaning that our customers apply using our DOA. Currently the portal does not allow to apply electronically in those cases. Will it be possible to review that?	Yes. We will take it on board of future improvements of the portal
<b>Airbus</b>	Is there any interface between the application portal and SEPIAC?	Yes. Application and approval will be manage through the application portal, while the intermediate (technical) activities will be managed by SEPIAC, and there will be interfaces between both.
	<u>Q&amp;A and Summary</u>	
	<ul style="list-style-type: none"> <li>• ASD is very satisfied with the side meetings. They were very valuable and improve communication and transparency.</li> <li>• Thales considers this as an excellent meeting. The new formula used is very good. For the second day it is proposed to present some sectorial topics (helicopters, avionics, etc.) as you did for the first day and also better balance between views authority/industry.</li> </ul>	Noted.
<b>QUESTIONS RAISED AFTER THE WORKSHOP</b>		
<b>RR Deutschland</b>	<p>1.2.2 Stakeholder Feedback</p> <p>- Is was not transparent to whom in the companies the EASA questionnaire was submitted in 2015 to provide a 'stakeholder feedback'.</p> <p>It would most likely help, if for 2016 the questionnaire will be formally</p>	The questionnaire was submitted to the DOA focal point (as known to the DOA Team Leader) within each design organisation. From EASA standpoint it is not desirable to send multiple questionnaires to one design organisation as it may affect the statistical results. If the focal point who receives the questionnaire is not responsible for all aspects of the questionnaire within the

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
Cologne, 18-19.11.2015

Organisation	Subject	Reply
	<p>submit to the HDO but also a copy to the Chief of Airworthiness Office and the applicable DOA Manager of the company.</p> <p>The Airworthiness Office for the Product Certification aspects and the DOA Manager for the DOA Implementation aspects.</p>	<p>design organisation, he/she is kindly requested to collect the input from his/her colleagues, and provide the design organisation's collective response in the questionnaire.</p>
<b>RR</b> <b>Deutschland</b>	<p>1.4 DOA ToA</p> <p>- The current ToA are restricted to the EASA scope of work.</p> <p>It would provide clarity, if the EASA would include acceptance of the EASA DOA under BASA to be formally recorded on the DOA ToA (i.e. to declare US, CAN and Brazil full or limited acceptance of these ToA).</p>	<p>The intent of the EASA DOA ToA is indeed to define the Scope of Work as approved by EASA.</p> <p>The proposal to include the BASA status is unpractical, e.g. if a change to a BASA would affect the aforementioned acceptance by another authority, then all ToA's would have to be re-issued...</p>
<b>RR</b> <b>Deutschland</b>	<p>1.5 Flight Test update</p> <p>- On page 26 there is a statement that the 'DO is the operator of the aircraft under test'.</p> <p>I think this statement is misleading and requires clarification. The operator of an aircraft is under the jurisdiction of the 'State of Registry' as per ICAO, while the DO should stay under the 'State of Design' jurisdiction.</p> <p>The DOA under the State of Design can't be made responsible for the FTOM of another legal entity (even with subcontract) which operates flights (for the purpose of testing) under a that State of Registry's responsibility (ref page 32).</p> <p>Could you please clarify the independencies between DOA and operators (even both might be the same legal entity, but not necessarily). E.g. Engine DOA holder but a/c flown by somebody else or in a different state.</p> <p>I assume FTOM is only applicable where the a/c is registered within the EU; and operator and DOA is the same legal entity?</p>	<p>The presentation material provided on the website has been used to illustrate and support the verbal presentation provided during the workshop. Wording used on the slides is therefore reduced to a minimum. In this specific case the actual statement provided during the workshop was that in order to better understand the concept of the FTOM requirement it should be understood that Part 21 'assumes' the DO is the operator of the aircraft under test (DO to be understood as the legal entity holding a (A)DOA).</p> <p>Acknowledging the fact that other operators might perform flight test activities on behalf of the Design Organisation, AMC to 21.A.143, 21.A.243, 21.A.14(b) 21.A.112B(b) and 21.A.432B(b) specifies that such "...contractors or sub-contractors (...) should comply with the FTOM of the primary organisation, unless they have established an FTOM in compliance with Part 21, the use of which has been agreed between the two organisations."</p> <p>This AMC thus introduces an acceptance criterion for contractors or sub-contractors to either agree on performing flights in accordance with the DO's FTOM or to provide an own FTOM meeting the requirements of 21.A.243(a). In the latter case the DO's responsibility is to check the FTOM's compliance with Part 21 before agreeing on its use.</p>

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
		In case of third country operators the same applies. Requirements of 21.A.243(a) should then be seen complementary to any national rules that the operator has to comply with. Applicability of Appendix XII may be limited (e.g. a national flight test rating/licence would probably be required by national law), which is acceptable i.a.w. 21.A.243(a)ii ("...in accordance with Appendix XII to this Annex I, where applicable;").
<b>RR</b> <b>Deutschland</b>	2.1 LOI update - Is there any intention to align the new ToA with the DO Performance criteria used for LOI?  - I assume, the proposed use of CMs as stated on page 12 will be for voluntary use only as a trial. Could you confirm that this is your understanding as well or provide your view.	Yes, the relevant EASA Working Groups have identified this potential and are discussing the feasibility to align these items. The proposed use of CMs is foreseen as an intermediate phase before the AMC/GM will be published.
<b>RR</b> <b>Deutschland</b>	2.3.1 OSD changes - Is my understanding correct, that OSD will not change engine TCs?	Yes, correct.
<b>RR</b> <b>Deutschland</b>	2.7 MRB process under DOA - The presentation doesn't distinguish between a/c DOA holder and others. What is the role of those other DOAs (e.g Engine TC) in such a MRB process?	The MRB Process is performed at A/C level. For the MRB Process, the Engine TC Holder (or any other major system providers – e.g. Landing Gear manufacturer) is considered as a "supplier" irrespective of them having their own DOA or not. We expect that the DOA applying for A/C TC is ensuring that the data produced or activities performed by its suppliers in support of the MRB Process is following the accepted DOA procedures and the supplier staff involved in these tasks have the proper qualification. In addition, specific verification / approval functions (authorised signatories) are properly assigned through nomination under the DOA procedure.
<b>RR</b> <b>Deutschland</b>	2.8 SEPIAC - Will the application for 'derivatives' be implemented as a 'Change to TC' (as	The development of SEPIAC is not yet at this level of detail. Question will be taken into account by the SEPIAC project team.

**Part 21 DOA Implementation and  
Product Certification Workshop**  
**- Industry session -**  
 Cologne, 18-19.11.2015

Organisation	Subject	Reply
	per EASA Form 31) or as a special case (as in the current portal)?	
<b>RR</b> <b>Deutschland</b>	2.9 Implementation of R376  - On page 9, the 72h requirement is used 3 times with a conflicting relationship. Is there a mistake?	No there is no mistake. Each step in the reporting chain is given 72h to make its report. Since the design organisation is depending on an observer to report the occurrence before it can start to make its report to the authority, this reporting chain may take longer than the reporting line by the observer directly to the authority. It is not required that both reporting chains will deliver a report at the same time.
<b>RR</b> <b>Deutschland</b>	2.10 SB related to AD CM 21_A_J_001  - The presentation doesn't clarify the differences between ADs written against parts and ADs written against registered aircraft. Could you confirm that the CM contains 'best practice' for a/c level only?	As stated in Chapter 2 (Background) of the Certification Memo: it is addressed at Design Approval Holders for Type Certificates, Supplemental Type Certificates and ETSO Approval.