COMMENT RESPONSE DOCUMENT (CRD) TO NOTICE OF PROPOSED AMENDMENT (NPA) 2010-01

for amending the Executive Director Decision No. 2003/1/RM of 17 October 2003 on acceptable means of compliance and guidance material for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (« AMC and GM to Part 21 »)

"Other party supplier control"

Explanatory Note

I. General

1. The purpose of the Notice of Proposed Amendment (NPA) 2010-01 was to amend Decision 2003/01/RM of the Executive Director of 17 October 2003[1] to develop AMC/GM material to paragraphs 21A.139 of Commission Regulation (EC) No 1702/2003[2] (Part-21) that will provide criteria for supplier surveillance and assessment by a party other than the POA holder.

II. Consultation

2. The draft Executive Director Decision amending Decision N° 2003/1/RM was published on the web site (http://www.easa.europa.eu) on 22 January 2010.

   By the closing date of 23 April 2010, the European Aviation Safety Agency ("the Agency") had received 50 comments from 20 National Aviation Authorities, professional organisations and private companies.

III. Publication of the CRD

3. All comments received have been acknowledged and incorporated into this Comment Response Document (CRD) with the responses of the Agency.

4. In responding to comments, a standard terminology has been applied to attest the Agency's acceptance of the comment. This terminology is as follows:

   - **Accepted** – The comment is agreed by the Agency and any proposed amendment is wholly transferred to the revised text.
   - **Partially Accepted** – Either the comment is only agreed in part by the Agency, or the comment is agreed by the Agency but any proposed amendment is partially transferred to the revised text.
   - **Noted** – The comment is acknowledged by the Agency but no change to the existing text is considered necessary.
   - **Not Accepted** - The comment or proposed amendment is not shared by the Agency

   The resulting text highlights the changes as compared to the current rule.

5. The Executive Director Decision amending Decision N° 2003/1/RM will be issued at least two months after the publication of this CRD to allow for any possible reactions of stakeholders regarding possible misunderstandings of the comments received and answers provided.

6. Such reactions should be received by the Agency not later than **01 December 2010** and should be submitted using the Comment-Response Tool at http://hub.easa.europa.eu/crt.

---

[1] Decision No 2003/01/RM of the Executive Director of the Agency of 17.10.2003 on acceptable means of compliance and guidance material to Commission Regulation (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production. Decision as last amended by Decision 2009/011/R of 24 August 2009.

[2] OJ L 243, 27.9.2003, p. 6. Regulation as last amended by Commission Regulation (EC) No 1194/2009 of 30 November 2009 (OJ L 321, 8.12.2009, p. 5).

IV. Main comment issues discussed in this CRD

7. Some commentators expressed a need for either specifically accepted standards or more detailed guidance in order to prevent the risk of inconsistent implementation or non-acceptance by different Competent Authorities.

   The Agency's position is that the AMC will remain at the level of criteria in order not to restrict its applicability to different existing and future industry standards and oversight schemes. Formal approval of organisations that perform the supplier assessment, audit and control is not possible because this is outside the remit of the Basic Regulation (Refer to article 1(a) of Regulation (EC) 216/2008), and can not be regulated within that rule. It is recognised that Competent Authorities will need to share experiences in order to achieve consistency, and this will be structured within the future Authority Requirements currently under development. For example, refer to the NPA 2008-22b paragraphs AR.GEN.025 and AR.GEN.030. The Agency plans to organise a workshop shortly after the publication of these AMC in order to exchange views and discuss consistent implementation

8. Comments show that the scope of this proposal is not always clear. Therefore it is repeated that the proposed AMC's provide criteria for a POA holder to meet their obligations under 21A.139(b)(1)(ii) by involving other parties in the activities of assessment, audit and control of a suppliers. These are the activities that establish if the **organisation** of a supplier is considered adequate for the job. This of course can also be applicable to only sub-set of the suppliers' organisation or specific production processes as is the case for Nadcap.

   Conformity of **products, parts, materials or equipment** to their applicable **design** is a different subject and should not be confused with conformity to the "certification standards" (like e.g. EN9100) used by the other party to "certify" the organisation. The conformity of products, parts, materials or equipment is covered in the quality system requirement by 21A.139(b)(1)(iii) with contribution as necessary from 21A.139(b)(1)(ii). The showing of the two "conformities" are however related and the conformity of an organisation to a standard like EN9100 could be a prerequisite for the method used to determine products, parts, materials or equipment conformity to design. For example, it could be appropriate for a POA holder to make use of identification of incoming documentation and data from the supplier relevant to the conformity of the parts from a well organised supplier. On the other hand a full scale incoming inspection by the POA holder could be necessary when there is no adequate control of that supplier.

IV. CRD table of comments, responses and resulting text

(General Comments)	-

comment	*7* comment by: *EUROCOPTER* Eurocopter has no comment on this NPA.
response	*Noted*

comment	*8* comment by: *FAA* The FAA has reviewed this NPA and has no comments.
response	*Noted*

comment	*9* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* The Swedish Transport Agency, Civil Aviation Department agrees to the content of NPA 2010-01.
response	*Noted*

comment	*25* comment by: *Embraer - Indústria Brasileira de Aeronáutica - S.A.* Embraer is quite pleased to see this EASA proposal to accept other party qualification and surveillance of suppliers, and believe that it will contribute significantly to improving safety by allowing authorities, POA holders, and suppliers to eliminate duplication of effort, thus saving resources that can be redirected to other safety matters.
response	*Noted*

comment	*28* comment by: *Sell GmbH* Sell welcomes this rulemaking task for acceptance of supplier assessment audit and control performed by other parties. As this rulemaking task is limited to Part-21 Subpart G Organisations only, Sell request EASA to extend the new guidance and advisory material to Part-21 Subpart J Organisations to assure uniform application of quality and process standards in design and production throughout Aviation Industry. For suppliers to Part-21 Subpart J Organisations respective standards should be considered, e.g. ISO 17025 for test houses.
response	*Partially accepted* Extending the AMC to "other party DOA control" is not within the scope of this task and can not be included without consulting a proposal in an NPA. EASA organised a workshop in 2006 on The Future of Design Organisation Approvals. One of the issues in that workshop was to seek the opinion of stakeholders with respect to third party certification. At that time it was not supported and the issue was closed. This issue has however surfaced again and is under discussion at EASA.

comment	*29* comment by: *Federal Office of Civil Aviation Switzerland/ pog* Due to the fact, of the fairly generic AMC's created in ths NPA, EASA should find a recommended conclusion with all NAA's to avoid disadvantages of suppliers in different member states On behalf of Simon Kaiser, Federal Office of Civil Aviation Switzerland, Gaël Poget
response	*Partially accepted* The AMC is kept at the level of criteria in order to be able to apply this to different existing and future industry standards and oversight schemes. Competent authorities will need to share experience as will be required by the future Authority Requirements. As an example refer to the NPA 2008-22b requirements AR.GEN.025 and AR.GEN.030. If required additional AMC, GM or standard practices will be developed at a later stage. EASA plans to organise a workshop shortly after the publication of these AMC in order to exchange views and discuss consistent implementation.

comment	*38* comment by: *Rolls-Royce plc [DGJ]* The term “needs to” is used on many occasions throughout the proposed text. This is ambiguous in that it is suggestive of a requirement but carries no compulsion. We would suggest using “shall” or, where compliance is recommended but not required, “should” or, where optional, “could” instead.
response	*Accepted* AMC is by definition is a means, but not the only means to show compliance to a requirement. Therefore the non-compulsory wording is used. However, for consistency with other AMC, the term "needs to" is replaced by "should".

comment	*39* comment by: *Rolls-Royce plc [DGJ]* The term “other party” is used variously throughout the text, which has led to some slightly clumsy phrases (eg “...procedures for using other party for supplier assessment...” instead of “...procedures for using other parties for supplier assessment...”) The term becomes particularly ambiguous when used in the sense of “another party” (ie is this the same “other party” or a different “other party”?). It would clarify the text if “a third party” were used throughout instead.
response	*Partially accepted* The term "other party" has been used in order to harmonise with the FAA order 8120.12 and is used instead of "third party" in order not to get confused with other tier suppliers. The term “third party” is often used in the context of the supply chain. In order to improve the readability an abbreviation (OP) will be introduced in the text for “other Party” specific for these AMC.

comment	*44* comment by: *Rolls-Royce plc [DGJ]* **AMC No. 2 to 21A.139(b)(1)(ii)**

Whilst we do not object to the principle of taking credit for independent oversight of a manufacturing supplier, we are concerned with the possible abuse to which such a system might be exposed.

In effect, this AMC introduces the concept of an accredited “Part-21G auditor” organisation. However, the NPA does not offer an established mechanism for granting such an accreditation which has the acceptance of the Agency. Neither does the NPA suggest any formal regulation of such a third party to ensure that it is (and remains) competent to issue certificates of compliance to a supplier, nor are there any defined standards against which to judge a prospective third party auditor.

This lack of clarity will, in practise, will lead inevitably to variation in application and, potentially, in standard. At its extreme, such variation may possibly have safety implications.

In this environment, we (as a POA-holder) would be very wary of engaging into such an arrangement because:

- We would not feel comfortable simply accepting the findings of an independent and unregulated entity over which we (as the POA-holder) have no direct control.
- Where a supplier is approved by an independent and unregulated entity, we do not understand how we (as the POA-holder) could show definitively that our quality system will ensure that parts produced by that supplier will conform to the applicable design data.
- It is not clear how a Competent Authority can find compliance with Part 21G if the standard to which the third party is accredited is not one they recognise. This might cause particular difficulty if the third party were based outside the EU and was working to its own national standards which had not been assessed by either the Agency or the Competent Authority. Alternatively, it might lead to a lack of standardisation if a Competent Authority insisted on use of its own national standards which differed from those elsewhere in the EU.

The best way we can see of making this arrangement work effectively for all parties is for the Agency to create a new type of Approved Organisation, authorised by EASA to carry out production supplier oversight to a given set of Agency requirements. However, in the absence of such arrangements, the Agency should, at the very least, publish a list of those accredited systems which are deemed “acceptable” (reflecting the phrase used in §13 (section IV) of the NPA) and/or define the detailed standards against which such third parties should be assessed, thereby promoting uniform interpretation.

response *Partially accepted*

The commenter is right that the NPA proposal does not provide a mechanism or standards for granting an "accreditation" to "Part-21 auditor". The main reason for this is that such “auditor” organisations are not within the scope of the Basic Regulation (Refer to article 1(a) of Regulation (EC)216/2008).
Instead the proposal provides possibilities to the POA to make use of Other Parties (OP) to perform some supplier audit and / or control activities on behalf of the POA without removing them from their Part-21 Subpart G

responsibilities.
Where POAs now apply their own standard to audit vendors and subcontractors, which does not improve standardisation, this AMC provides criteria to use OP to perform those audits. Because these OP are specialised in this activity and use common standards, this is expected to enhance the auditing process and lead to generally higher quality standards that are standardised over participating suppliers.
The findings of the OP should not be simply accepted without due review by the POA. The AMC is intended for the POA to provide criteria that will enable the POA to have confidence in the OP and that the functions performed by the OP result in an equally or better oversight of the vendor or subcontractor. To keep track of the certification status of the OP, the criteria (3)(vi) and (5) are in this respect important.
Also important for the understanding of this proposal is the scope. These AMC are to 21A.139(b)(1)(ii) Vendor and subcontractor assessment audit and control, which do not cover for instance “Non conforming item control (21A.139(b)(1)(viii) or 21A.139(a).

TITLE PAGE p. 1

comment *4* comment by: *TURBOMECA*

As EAQG member, we accept and support the proposed NPA, we have already commented it during its preparation.

response *Noted*

comment *5* comment by: *Chris LYDDON*

I would like to see an obligation on the POA holder to make an appropriate contribution into the other party oversight scheme. This would enable the POA holder, who declares that they are using the other party scheme to partly replace their own surveillance, to demonstrate compliance with the requirement to ensure that his suppliers are being asessed and suveilled properly by the other party organistion. (ref AMC2 section 3 (c) (3) (iii).

Appropriate contribution could be determined as a Industrial Representatives time committed against the size of the organisation.

Note: the ecomonic impact on page 9 states "In certain industry schemes (like ICOP) a POA holder will need to make some resources available to participate in industry control. " However there is no requirement in the document

response *Not accepted*

Economic obligations for a POA to contribute to an industry system will not be imposed by safety regulations. The referred sentence on page 9 of the NPA only indicates that sometimes an economic impact can be expected because of the obligations on members of certain schemes.

A. Explanatory Note - I. General p. 3

comment *27* comment by: *Swiss International Airlines / Bruno Pfister*

	SWISS Intl accepts the NPA 2010-01 without further comments.
response	*Noted*

A. Explanatory Note - III. Comment response document p. 4

comment	*2* comment by: *Dassault Falcon Service* DFS in general supports any regulation activity in order to improve quality system. We have no comment concerning this NPA for POA. But we would like to take this opportunity to mention that this option to audit supplier by a other party could be extended to some suppliers providing tasks for Design Organisation and more especially a supplier performing laboratory fire testing due to some findings within these laboratores. Although that these suppliers are in fact part of the Design Organisation and must be monitored as required by Part 21 regulations (21A.33 Investigation and tests, 21A.239 Design assurance system, 21A.243 Data), this control of all laboratories providing testing activities for DFS could create some difficulties for some minor DOA like DFS. Today some laboratory performing fire test for DOA are audited by local authority but this is not acceptable for EASA! So could we imagine that EASA could extend this NPA to these laboratories performing fire testing tasks for DOA? The monitoring authority would be EASA.
response	*Partially accepted* Extending the AMC to "other party DOA control" is not within the scope of this task and cannot be included without consulting a proposal in an NPA. EASA organised a workshop in 2006 on The Future of Design Organisation Approvals. One of the issues in that workshop was to seek the opinion of stakeholders with respect to third party certification. At that time it was not supported and the issue was closed. This issue has however surfaced again and is under discussion at EASA.

A. Explanatory Note - IV. Content of the draft opinion / decision p. 4-6

comment	*24* comment by: *CAA-NL* The Netherlands sympathises with attempt to solve the problem targeted in the NPA and that is stated in the NPA as follows: “The inefficient situation where a supplier is audited by several POA holders on his quality management system. Moreover, current business concepts are based on large networks of industrial partners, contractors and sub-contractors, including 1st tear, 2nd tear, 3rd tear suppliers or even further. It is very demanding for the POA holders to ensure proper oversight of such a network.” However the CAA-NL is against the proposal to solve this problem as laid down

in this NPA For the following reasons:

1. Aviation safety is amongst others based upon 3 cornerstones:
   a. Responsibility for the product delivered;
   b. A thorough quality systems; and
   c. Monitoring of it by an independent authority.

The deliverer of a product is fully responsible for all the work performed under his approval and thus quality system but also only the work performed under his approval, including al subcontracting. The primary goal of the quality system is to produce, maintain, etc. safe products, fit for the use intended. Monitoring by an independent authority assures that the quality of the quality system fulfils the minimum requirement level.
AS/EN 9100 requires a quality management system. However there is a fundamental difference between a quality system and a quality management system. A quality management system is a risk management tool that aims for continuous improvement. And it does not guarantee that there is a quality system that meets a minimum requirement level.

2. Industry standards can be very useful, but per definition for specific parts of the quality system. In that respect the use of EN 4179 for non-destructive testing is a good example. NADCAP-certification of special processes also qualifies for that.

3. The effect of the proposal upon the responsibilities is unclear. The proposal gives the opportunity to perform the evaluation and monitoring of the subcontractor partly by another party, accredited under a different system. Difficulties arise when this other party accepted details that are not acceptable by the POA holder or its Competent Authority.

4. Our experience with the present AS/EN 9100 reveals that a quality management system of an organisation in no way guarantees that the organisation has a proper functioning quality system. On the contrary, the CAA-NL has a number of examples in which the organisations have EN/AS 9100 approvals but are not able to show compliance or have great difficulties in showing continued compliance with Part 21 and/or Part 145. Also in several occasions the independence of the surveillance is quite questionable.
   As an extensive part of the production nowadays takes place at subcontractors, therefore the quality at the subcontractors is very important for the quality of the end product. As such the proposal will have a negative impact on safety.

5. The proposal is made for Part 21 Production. However as soon as it becomes available for production, it will establish a precedent for other parts of the aviation regulations. The large networks of industrial partners, contractors and sub-contractors, including 1st tear, 2nd tear, 3rd tear suppliers or even further also exists in the field of maintenance. However the solution for the current situation can be found there also.

6. A proper root cause analysis has not been performed nor has a survey in adjacent activities been executed. If we do this we discover that 21A.133 Eligibility restricts the number of POA holders. And as a consequence is a major contributing factor of the high number of subcontractors in production.
   In the area of Part 145 maintenance we see that this problem does not

exist, at least not to the same extent. In Part 145 there are no restrictions for eligibility, resulting in much more MOA holders than POA holders. Even in the field of component maintenance, or special services while these organisations per definition are a supplier to a MOA holder with an A-rating.

Therefore the CAA-NL disagrees with the proposal and proposes the following alternative. The eligibility restrictions for POA as laid down in GM 21A.133(a) third bullet should be alleviated. Therefore CAA-NL suggests changing the current text:

~~• It is not the intent of the Competent Authority to issue approvals to manufacturing firms that perform only sub-contract work for main manufacturers of products and are consequently placed under their direct surveillance.~~

Into:

• Manufacturing firms that perform only sub-contract work for main manufacturers of products may apply for their own POA, specifically when they work for different main manufacturers and would otherwise suffer a multitude of surveillance.

Furthermore item 6 of the second bullet of the same GM, may be interpreted or rephrased in the line of 'Parts must meet a specific approved design to meet specifics from the applicable CS.' Thus have better alignments with the last bullet of this paragraph.

response

Partially accepted

EASA supports the view that the three cornerstones presented are important especially in the light of the proposed AMC.
The following general remarks that relate to the three cornerstones should therefore be clear.
a. The responsibility of the POA does not change with the introduction of these AMC. It provides criteria that the POA should consider when using Other Party (OP) assessment and audits of suppliers.
b. The quality system of the POA is not replaced by acceptance of quality management systems. The POA can benefit from existing quality standards and oversight of the application of these standards when they result in an equal or better assessment and audit of their suppliers.
c. Monitoring of the POA by the Competent Authority is unchanged. Monitoring of the OP by the POA should be covered in this oversight.

Responses/reactions to the specific comments:

2

This comment highlights the risk that specific standards (e.g. an Audit checklist) can be confused with acceptance of more generic systems (e.g. EN 9100).
The statements in AMC No. 1 and 2 regarding the use of EN 9100 is therefore amended, and compliance to (i) is not deemed to be met. The POA would need to verify the scope of the checklists that will be used by the OP.

3

As mentioned above, the responsibilities remain with the POA. Review of the findings from the OP will be considered as the POA's responsibility. This is also why criteria (c)(5) exists in the AMC No. 1 and (c)(5) and (6) in AMC No. 2.

4

The AMC gives some credit to existing scheme's that use EN9100 series

standards within the European accreditation system. This provides an oversight that is sufficiently independent from the manufacturer. Also taking into account that the scope of these AMC's is assessment and auditing of suppliers, an impact on the safety of the products is not expected. Also refer to the Regulatory Impact Assessment in the NPA.

5

Future use of this approach can be expected, especially when Organisation Requirements (For different types of organisations) become more harmonised. This is seen as a development that would support the growing global character of aviation industry. A separate task will be required to review this development and its impact.

6

Increasing the scope of eligibility for POA is not within the scope of this rulemaking task and is not seen as the sole solution of other party involvement for POA holders. This AMC addresses the existing situation where industry has implemented other party that perform a service in supplier assessment and control.

A. Explanatory Note - The envisaged change to Decision 2003/1/RM/ AMC and GM to Part-21 p. 6

comment

6 comment by: *BAE SYSTEMS-MAS*

Last paragraph of section 13
suggest amendment to read

-Suppliers holding a special process certificate of approval issued under an acceptable accredited system (e.g. NADCAP/NUCAP).

response

Not accepted

The explanatory note of the NPA will not be re-published and therefore not changed. On the other hand, examples like Nadcap and NUCAP would be potential candidates provided that the requirements of the applicable AMC are complied with.

A. Explanatory Note - V. Regulatory Impact Assessment p. 6-11

comment

1 comment by: *Francis Fagegaltier Services*

At the end of paragraph V 17 we find the following : "Also suppliers in countries where the other party assessment and surveillance is not (yet) accepted by the Competent Authorities have a disadvantage."
Contrary to the USA where FAA is unique, in EU there are 27 Competent Authorities, which are in charge of delivering POAs, and EASA, which itself is in charge of some POAs (in non-EU foreign countries and to some rare EU POA holders).
These proposals would be easily understood when all suppliers are in the same country as the POA holder : there is one unique "Competent Authority".
It is a bit more difficult when suppliers are spread all over European Union : there is one competent authority for delivering the POA but there is one competent authority per country. How should the above noted sentence be understood in such a case ?
The case of a POA holder located within EU using some production facilities in

foreign (non-EU) countries as suppliers (as an example to illustrate a possible case : there is a production facility in Ouzbekistan which one day may be of interest for an EU production organisation). The above noted sentence raises questions in such a case. Could we have a situation where the competent authority of EU country n°1 has accepted the other party assessment and surveillance in the foreign country and the competent authority of EU country n°2 has not ? Is this independant of any discussion on bilateral agreement between EASA/EU and the foreign National authority ?

response *Noted*

The sentence at the end of paragraph 17 is addressing the situation where the Competent Authority of the POA would not grant benefits from Other Party oversight in a foreign country. This could be the case when there is no experience or confidence in the other party controlled oversight in that country. The initial familiarisation and implementation between EU Member State NAA could also create such a start-up issue. EASA therefore intends to organise a workshop soon after the publication of these AMC's.

comment *16* comment by: *UK CAA*

Page 6, Paragraph No: 14

Comment: It is understood and appreciated that the scope of NPA 2010-01 is currently limited to POA holders. However, bearing in mind the EASA horizontal rule philosophy, this NPA was also reviewed with the future regulations for aerodromes and their third party suppliers in mind. This comment merely wishes to point out that this approach might present difficulties for aerodromes on two grounds; first, they do not have contracts with most ground handlers (and to do so would presumably involve significantly altering the IATA handling arrangements); second, the aerodrome may not have competence in many areas of ground handling and therefore could not set standards.

Justification: See above. The NPA/RIA would need to be reconsidered if in future applied to aerodromes.

response *Noted*

As mentioned, the comment is out of scope for the moment, It will however be passed on to the appropriate rulemaking department.

Note:
The NPA proposal concerns the involvement of other parties within the responsibility of a POA. It would not qualify for activities outside of that scope. This is, as pointed out in the comment, an important difference with the competence of aerodrome.

comment *30* comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
RIA § ii economic – option 2

2. COMMENT:
The RIA is based on the assumption of a "common other party". But in case that several POA holders use several different "other party", the expected benefit is not so obvious. It's true the NPA gives flexibility by adding a new

"tool" but the impact of this tool on economy is not obvious.

3. JUSTIFICATION:
in order for the POA to have a control of the party's used standards and methods, the POA shall provide him with his requirements.

response *Noted*

The RIA is based on the assumption that this tool will reduce the duplication of oversight on suppliers by different POA holders. When these POA holders all would select a different Other Party and apply AMC No 1 there would indeed be little benefit. A reaction from the supplier in that case who would become subject to these parallel audits could be expected.
AMC no 2 would however reduce the duplication of oversight because a supplier is unlikely to hold several industry certificates issued by several Other Party organisations. A supplier would hold one EN9100 certificate only.

B. Draft Decision - GM No. 2 to 21A.139(a) p. 12-13

comment *3* comment by: *Agusta SpA*

In some cases the organisations and the competent authorities assign different meanings to the words "vendor" and "subcontractors". In order to avoid this a clear definition should be included in the GM No. 2 to 21A.139(a). What above also on the basis of the current wording used in the Regulation, that could lead to misunderstandings:

1. in 21A.139(b)(1)(ii) reading "[...] vendor and subcontractor [...]" it correctly appears that "suppliers" means "vendors and subcontractors"
2. in 21A.157 reading "[...] partners and subcontractors [...]" it appears that "subcontractors" means "suppliers"; the same in 21A.159(a)(1) reading "[...] partners or subcontractors [...]"
3. in 21A.165(h) reading "[...] partners, suppliers and subcontractors [...]" it appears that "subcontractors" are not "suppliers"

response *Not accepted*

The note in the new AMC's is introduced to improve the readability of the AMC. A consistent use of "vendor and sub-contractor" from the requirement 21A.139(b)(ii) would make the text over complicated.
It is not supported that a definition is required to improve the understanding of this AMC.

comment *17* comment by: *UK CAA*

Page 12, Paragraph No: GM No 2 to 21.A.139(a)

Comment: As detailed in paragraph 1, the POA holder is responsible for determining the acceptance standards for physical condition, configuration status and conformity of supplied products etc. As these obligations do not change even if other parties perform an element of the supplier control, the POA holder may be required not only to have oversight of the supplier but will also be required to have oversight of the other party. This will introduce an additional cost and burden on the POA holder.

In order to minimise the burden on the POA holder, it is proposed to

differentiate between vendors and sub-contractors. This will enable the use of the other party scheme to control vendors and allow the POA holders quality system to concentrate on performance of sub-contractors.

Justification: Minimise burden on POA holders

Proposed Text to Second Para of GM No 2 to 21.A.139(a):
'To discharge this responsibility the quality system needs an organisational structure and procedures to adequately control vendors and sub-contractors. Elements of the quality system for the control of vendors may be performed by other parties provided that the conditions of AMC …'

response

Not accepted

It is true that introduction of supplier oversight by Other Parties (OP) will cause additional cost and work for the POA holder. When the use of OP is in place, the costs and burden for oversight of vendors and sub-contractors is expected to reduce.
Restricting the applicability of these AMC to vendors only is not supported because benefits are also expected when oversight is performed by the OP on sub-contractors.

comment

40 comment by: *Rolls-Royce plc [DGJ]*

The first bullet of the first list of items has been amended to require qualification and audit of a supplier's "procedures" rather than their "quality system". We disagree with this proposed change. We feel that it is extremely difficult to audit a supplier's procedures without gaining a proper understanding of the supplier's organisational structure. Procedures will describe "who" does "what", but knowledge of the organisational structure is required to assess the suitability of those individuals carrying out the tasks. Noting that the proposed new AMCs identify that a "quality system needs an organisational structure and procedures", we recommend returning to the original text:
"qualification and auditing of supplier's quality system ~~procedures~~,"

response

Accepted

The sentence was changed because it is not required to do an audit on the whole of the suppliers' quality system when only part of that system would have influence on the parts supplied to the POA.
In order to determine which procedures could impact on the parts that are provided by the supplier, it is true that a proper understanding of the quality system would be required.
The comment is accepted because the proposed change to "procedures" could lead to an insufficient review of the quality system. The current text, including the line before the first bullet point *("Control can be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity))*, already reflects that the appropriate elements of the quality system need to be considered.

resulting text

GM No. 2 to 21A.139(a)

Quality System – Conformity of supplied parts or appliances

The POA holder is responsible for determining and applying acceptance

standards for physical condition, configuration status and conformity of supplied products, parts or appliances, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.

To discharge this responsibility the quality system needs an organisational structure and procedures to adequately control ~~external~~ suppliers. Elements of the quality system for the control of suppliers may be performed by other parties provided that the conditions of AMC No. 1 or No. 2 to 21A.139(b)(1)(ii) are met.

Control can be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity).

- qualification and auditing of supplier's quality system,
- ….

B. Draft Decision - AMC No. 1 to 21A.139(b)(1)(ii) p. 13-14

comment *10* comment by: *Airbus SAS*

Airbus is commenting on:
AMC No.1 to 21A.139(b)(1)(ii), Para 3 (c) (3), last sentence:
"If the POA holder uses another party participating in a certification scheme based on the **AS/EN 9100 series** standards and recognised by the European Accreditation as complying with the general Community rules and policies for such schemes it is deemed in compliance with items (i), (ii), and (iv)."

Airbus proposes to replace in this sentence:
"AS/EN9100 series" by **"AS/EN/JISQ 9100 series or equivalent"**

Rationale for this proposal:
In the Asia/Pacific sector, the IAQG standards are distributed by another distribution body and have another numbering system: in particular, EN or AS9100 is replaced by JIQS 9100, with same content but another name and may be translated in Japanese or another language, and ICOP scheme perfectly recognizes the equivalence. This might be extended in the future with some countries (China, Korea, etc) that are part of IAQG and might decide to also have their own specific equivalent standard in their own language. Not recognizing this equivalence would mean that for instance Airbus would not be able to use the privileges of the NPA for Asia/Pacific suppliers that have a JISQ9100 certificate.

response *Partially accepted*

The JISQ standard is not added because it is not used by the recognised signatories to the EA MLA. For consistency this also means that the AS standard will be deleted.
This however does not obstruct the use of this AMC when the JISQ or AS standard is used. The main difference is that compliance with the referred items (ii) and (iv) is not deemed to be met.

comment *12* comment by: *European cooperation for Accreditation*

Point 3(c)(3) final paragraph: Delete: "... recognised by the European Accreditation as ...". Insert: "... recognised under the accreditation of a

signatory to the European cooperation for Accreditation (EA) Multilateral Agreement as ...".

response *Partially accepted*

The text is amended to more clearly reflect that verification of the specified conditions is deemed to be met when the OP is an accredited signatory of the Multilateral Agreement with EA for the scope of their oversight.

comment *14* comment by: *Luftfahrt-Bundesamt*

Comment to 3 Conditions and criteria ... (2):
The term „(…) made available to the Competent Authority upon request" should be replaced by a clear requirement. As part of the approval process of the significant change the competent authority should check the listings of suppliers under surveillance by the other-party.

Comment to 3(3)(ii):
Which experience or knowledge is present to the initiator of this AMC about the functioning of other-party systems?
As long as there is no defined and legally binding demand regarding the standard of the other-parties how shall the competent authorities be able to safeguard that the other-party systems run successfully.

Comment to 3(3)(iii):
The most influential other-party systems base on applying DIN EN AS 9001 or 9100 which determine a three-years period for a complete survey. By this demand an individual surveillance frequency is basically excluded. Which would be the authority's means for exerting an influence if the re-certification period was expanded by standardisation into a cycle of five years for example?
Regarding this point the AMC should include a clear demand for the maximum surveillance period.

Comment to the paragraph following 3(3)(v):
The term „based on the AS/EN 9100" should be replaced by „in compliance with AS/EN 9100".

Comment to 3(4):
„Indication" is not strong enough and should be replaced by the word „definition".

response *Partially accepted*

Comment to 3 Conditions and criteria ...(2)
The AMC is written for the POA in order to comply to the requirements. It is however up to the Competent Authority in accordance with 21B.220(c) to define the approval procedures.

Comment to 3(3)(ii)
The drafting group is aware of the limited experience that is currently available on Other Party (OP) schemes. However current experience should not be used as a guarantee for future performance of such a scheme.
This AMC does not request the Competent Authority to monitor the OP **system**. This would be outside of the remit of the Basic Regulation. The Competent Authority does need to include the activity of the OP as a supplier of quality functions in the scope of the oversight of the POA. The day to day "value" and confidence in an industry system for certified suppliers will be

depending on the experience gained by Competent Authorities. It is therefore important that this experience is shared between Competent Authorities. Future Authority Requirements (Refer to the response comment 29 on page 5 of this CRD) should provide a structured approach.

Comment to 3(3)(iii):
Part-21 Subpart-G does not require a specific frequency for **supplier** audits by a POA holder. The oversight of the supplier by the POA should however be accepted by the Competent Authority.

Comment to the paragraph following 3(3)(v)
It is accepted to change the sentence in order to more clearly say that EN 9100 series standards meet the specific requirements.

Comment to 3(4)
It is accepted to change the sentence as suggested.

comment *18* comment by: *UK CAA*

Page 13, Paragraph No: AMC No 1 to 21.A.139(b)(1)(ii), paragraph 1

Comment: This paragraph requires the POA holder to enter into an arrangement with the other party, however there is no guidance on the minimum requirement for such an arrangement.

Justification: Insufficient guidance to enable the POH holder or the competent authority to make or evaluate such arrangements.

response *Not accepted*

The AMC is written at a level that allows it to be applied to various types of "outsourcing" oversight activities to Other Parties (OP). This is why specific details can not be provided.

comment *19* comment by: *UK CAA*

Page 13, Paragraph No: AMC No 1 to 21.A.139(b)(1)(ii), paragraphs 3(a) & (b)

Comment: If the POA intends to make use of other parties for supplier assessment, they are responsible for ensuring the other parties supplier assessment and surveillance process and procedures are in compliance with Part 21. Given that the other party may be carrying out this supplier assessment for a large number of POA holders, how are they expected to ensure their procedures meet the requirements of all the POA holders quality systems?

By using the other party to conduct the supplier surveillance, they will be required to be audited by all of the contracted POA holders. The burden of auditing will shift the multiple audits from the supplier to the other party, therefore severely limiting the benefit of such a system.

By changing the emphasis from suppliers to vendors, the problem identified above will largely disappear. It is recognised that POA holders will continue to be required to carry out product audits and therefore be able to discharge their responsibilities under 21.A.139(b)(1)(ii).

Justification: Simplification of the regulations for POA holders.

response

Noted

The comment assumes that there are Part-21 requirements for other party supplier assessment and surveillance processes and procedures. This is however only true at a high level requirement of 21A.139(a). Because there are many different set-ups of supplier/POA production links, GM No. 2 to 21A.139(a) provides a list of techniques that can be applied in the control of suppliers. There are only Part-21 requirements for the POA and (as stated in this GM No. 2) a supplier who does not hold a POA is considered as a sub-contractor under the direct control of the POA quality system. The quality system of the POA (contained in the POE) will detail how that control is established.
The comment that the other party could become subject of audits from all contracted POA holders is true. This is however still considered to be a substantially lower number when compared to the multiple audits at the suppliers' level.
It is important, as mentioned in the comment, that the suppliers' organisational assessment, audit and control does not replace product audits.

comment *20* comment by: *UK CAA*

Page 14, Paragraph No: AMC No 1 to 21.A.139(b)(1)(ii), paragraph 3(v)

Comment: With respect to sub-contracted manufacturing, it is impractical for the 'other party' to work from proprietary information supplied by more that one POA at any one time. How will the other party satisfy each POA holder's requirements?

By changing the emphasis from suppliers (that include sub-contractors) to vendors, the problem identified above will disappear.

response

Not accepted

AMC No. 1 is drafted for a specific contract between the POA and the OP. The contract should contain these details.
The scope of the AMC is consistent with the requirement and is not limited to vendors only for that reason.

comment *21* comment by: *UK CAA*

Pages 14 & 16, Paragraph No: AMC No 1 to 21.A.139(b)(1)(ii), paragraph (d) & AMC No 2 to 21.A.139(b)(1)(ii), paragraph (c) respectively

Comment: These paragraphs require the POA holder to make arrangements that allow the competent authority to make investigations in accordance with 21.A.157 to include other party schemes, however section B has not been revised to take this into account.

It is suggested that GM No 1 to 21.B.220(c) is revised to specifically address other party schemes.

Justification: Clarity of regulation

Proposed Text to GM No 1 to 21.B.220(c) 1st bullet
'Following the acceptance of the application and before commencing an investigation, the Competent Authority should, for the preparation and planning of the investigation:

- identify the site locations, including consideration to other party schemes needing investigation, taking into account the scope of any other POA issued by a Member State, which are valid in the circumstances.'

response

Not accepted

It is supported that the identification of site locations needing investigation should also consider including the site(s) of other parties involved in the oversight of vendors and sub-contractor assessment. This is however applicable to the other party, not for the OP **scheme**.
The GM is however not amended because this is considered included in the current wording "site locations needing investigation". A specific change for OP only would raise other discussions on e.g. vendor and supplier locations.

comment

31 comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
AMC No 1 to 21A.139(b)(1)(ii)
Paragraph §3(c)(3)(i)

2. COMMENT:
Standards and check lists used by the other party must be not only accepted but defined by the POA holder.

3. JUSTIFICATION:
in order for the POA to have a control of the party's used standards and methods, the POA shall provide him with his requirements.

response

Not accepted

Requiring that the checklists are defined by the POA is too restrictive. There could be acceptable check lists that are not defined by the POA. The POA should therefore verify that the checklists are acceptable. Either their own or defined by others.

comment

32 comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
AMC No 1 to 21A.139(b)(1)(ii)
Paragraph §3(c)(3)(ii)

2. COMMENT:
The qualification of the other party should be more detailed, with for instance a reference to applicable and recognised standards.

3. JUSTIFICATION:
Purpose of the comment is to clarify "appropriately qualified". The means by which qualification is achieved should be documented and a copy kept by the POA holder.

response

Not accepted

The AMC is kept at the level of criteria in order to remain applicable to different existing and future industry standards and oversight scheme's. EASA Standardisation will be used to gain and share future experience from NAA's. If required additional AMC, GM or standard practices will be developed.

comment

33 comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
AMC No 1 to 21A.139(b)(1)(ii)
Paragraph §3(d)

2. COMMENT:
Some guidance about competent authority investigation on other party activities could be developed for standardisation purpose in AMC/GM of section B.

response

Not accepted

The AMC is kept at the level of criteria in order to be able to apply this to different existing and future industry standards and oversight schemes. Competent authorities will need to share experience as will be required by the future Authority Requirements. As an example refer to the NPA 2008-22b requirements AR.GEN.025 and AR.GEN.030.
If required additional AMC, GM or standard practices will be developed at a later stage. EASA plans to organise a workshop shortly after the publication of these AMC in order to exchange views and discuss consistent implementation.

comment

41 comment by: *Rolls-Royce plc [DGJ]*

§Note
Through the introductory "Note", both proposed AMCs seek to define "vendor", "sub-contractor" and "supplier" as being fully interchangeable terms. However, it is our understanding that some organisations interpret the text in GM No. 2 to 21A.139(a) as defining a "sub-contractor" as being a supplier which does not hold a POA. Although we find this interpretation unhelpful and do not agree with it, if the Agency's intention is to define a "sub-contractor" as a supplier which does not hold a POA, we would suggest that the "Note" in both AMCs be clarified as follows:

> "For the purposes of this AMC only, vendors and sub-contractors are hereafter referred to as "suppliers", regardless of whether or not they hold a POA..."

Separately, if such definitions are intentional, consideration should be given to explicitly defining these terms ("vendor", "sub-contractor" and "supplier") as part of the task to transcribe Part 21 into the new structure (task MDM.060), and ensuring their appropriate and correct use throughout both the regulation and advisory material.

response

Partially accepted

The note is introduced in order to simplify the wording of the AMC and at the same time to be consistent with the requirement 21A.139(b)(1)(ii).
The issue that is raised is not within the scope of this NPA, but at the level of 21A.139(a). The line in 21A.139(a) "...partners, or supplied from or

subcontracted to outside parties…" is considered independent from the type of arrangement (making it a vendor or sub-contactor) or whether such an organisation has a POA. The GM No. 2 to 21A.139(a) is drafted in the same understanding where only a reduction of control of such a POA carrying supplier is granted.
The comment does show that interpretation issues could exist and therefore the note is slightly changed as reflected in the resulting text.

comment

42 comment by: *Rolls-Royce plc [DGJ]*

§3(c)(3)(ii)

This text seems to imply that the third party is an individual (although this may not have been intentional). If, however, the work were contracted to a medium sized organisation, we believe that the POA-holder should also ensure that the third party were adequately resourced, suitably organised and having an appropriate authorisation process to ensure that the right individuals were conducting the supplier surveillance. We suggest that the text should read…

(ii) Verification that the ~~other~~ third party is appropriately qualified (or, in the case of an organisation, is resourced and organised to ensure that any employee that it authorises to conduct supplier surveillance is suitably qualified) and has sufficient knowledge, experience and training to perform ~~its~~ their allocated tasks.

The suggested amendment also reflects comment 39 regarding the use of "other party".

A similar comment may be applied to the corresponding text in AMC No. 2 to 21A.139(b)(1)(ii).

response

Not accepted

For harmonisation with the FAA, the term "other" party is kept. The Agency does not agree that the wording implies that the other party is an individual.
The commentator is right that, appropriate to the scope of work and organisation, the mentioned aspects of an OP organisation might need to be considered.
This is however considered too detailed and dependant on the OP for these AMC's.

comment

43 comment by: *Rolls-Royce plc [DGJ]*

§3(c)(4)

Please confirm that this clause is intended to cater for the situation where:

- A third party carries out surveillance of a supplier's quality system which defines "who" does "what" and "how", and what records are kept (this could be assessed by a quality system auditor); and

- The POA-holder continues to carry out surveillance of the supplier's

competency (capability) to carry out particular types of work (this would need to be assessed by someone familiar with the manufacturing processes employed).

A similar comment may be applied to the corresponding text in AMC No. 2 to 21A.139(b)(1)(ii).

response

Noted

This clause is indeed intended to make sure that no gaps will occur between the assessment, audit and control performed by the OP and the POA holder.

resulting text

AMC No. 1 to 21A.139)b)(1)(ii)

Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using documented arrangements with other parties for assessment and surveillance of a supplier.

1 General

Note

For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as "suppliers", regardless of whether or not they hold a POA and audit and control is hereafter referred to as "surveillance".

The production organisation is required by Part-21 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The use of Other Parties (OP), such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the POA holder from its obligations under 21A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The use of OP to perform supplier assessments and surveillance should be part of the production organisation quality system and fulfil the conditions of this AMC.

This AMC is applicable to a method whereby a POA holder has a documented arrangement with OP for the purpose of assessing and/or surveying a POA's supplier.

2 Approval by the Competent Authority.

Implementing or changing procedures for using OP for supplier assessment and surveillance is a significant change to the quality system and requires approval in accordance with 21A.147.

3 Conditions and criteria for the use of OP to perform supplier assessment and surveillance.

(a) The POA holder should include the use of OP for supplier assessment and surveillance in the POA holders' quality system to demonstrate compliance with the applicable requirements of Part-21.

(b) Procedures required for using OP for supplier assessment and surveillance

should be consistent with other procedures of the POA holders' quality system.

(c) Procedures of the POA holder that uses OP to perform supplier assessment and surveillance should include the following:

(1) Identification of the OP that will conduct supplier assessment and surveillance.

(2) A listing of suppliers under surveillance by the OP. This listing should be maintained by the POA holder and made available to the Competent Authority upon request.

(3) The method used by the POA holder to evaluate and monitor the OP. The method should include the following as a minimum:

(i) Verification that standards and checklists used by the OP are acceptable for the applicable scope.

(ii) Verification that the OP is appropriately qualified and have sufficient knowledge, experience and training to perform their allocated tasks.

(iii) Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.

(iv) Verification that the suppliers' assessment and surveillance is conducted on-site by the OP.

(v) Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers' functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the other party assessment and surveillance, the items (ii) and (iv) shall be deemed to be complied with.

(4) A definition to what scope the OP will conduct suppliers' surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.

(5) The procedures used by the OP to notify the POA holder of nonconformities discovered at the suppliers facility, corrective action and follow-up.

(d) The POA should make arrangements that allow the Competent Authority to make investigation in accordance with 21A.157 to include OP activities.

B. Draft Decision - AMC No. 2 to 21A.139(b)(1)(ii) p. 15-16

comment *11* comment by: *Airbus SAS*

Airbus is commenting on:
AMC No.2 to 21A.139(b)(1)(ii), Para 3 (c) (3), last sentence:
"If the POA holder uses another party participating in a certification scheme based on the **AS/EN 9100 series** standards and recognised by the European Accreditation as complying with the general Community rules and policies for such schemes it is deemed in compliance with items (i), (ii), and (iv)."

Airbus proposes to replace in this sentence:
"AS/EN9100 series" by **"AS/EN/JISQ 9100 series or equivalent"**

Rationale for this proposal:
In the Asia/Pacific sector, the IAQG standards are distributed by another distribution body and have another numbering system: in particular, EN or AS9100 is replaced by JIQS 9100, with same content but another name and may be translated in Japanese or another language, and ICOP scheme perfectly recognizes the equivalence. This might be extended in the future with some countries (China, Korea, etc) that are part of IAQG and might decide to also have their own specific equivalent standard in their own language. Not recognizing this equivalence would mean that for instance Airbus would not be able to use the privileges of the NPA for Asia/Pacific suppliers that have a JISQ9100 certificate.

response *Not accepted*

The JISQ standard is not added because it is not used by the recognised signatory's to the EA MLA. For consistency this also means that the AS standard will be deleted.
This however does not obstruct the use of this AMC when the JISQ or AS standard is used. The main difference is that compliance with the referred items is not deemed to be met.

comment *13* comment by: *European cooperation for Accreditation*

Point 3(c)(3) final paragraph: Delete: "... recognised by the European Accreditation as ...". Insert: "... recognised under the accreditation of a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement as ...".

response *Partially accepted*

The text is amended to more clearly reflect that verification of the specified conditions is deemed to be met when the OP is an accredited signatory of the Multilateral Agreement with EA for the scope of their oversight.

comment *15* comment by: *Luftfahrt-Bundesamt*

Comment to 1 General, 2nd paragraph:
What does in this context „appropriately recognised or accredited“ mean? Who is setting the standards if there is no legal basis for giving the authorization to a governmental instance? Where are the standards defined? It would be consequent to implement a new part of the regulation 1702/2003 for certifying other-parties. This would be a legal basis on which the authorities would keep control and could take influence on the progress of supply chain control.

Comment to 1 General, 2nd paragraph, last sentence:
„Periodic follow-up evaluations“ is not a very precise term. The periodic follow-up evaluations should be defined by the legislative body. As an orientation the 24-months cycle of Part-21 surveillance or the 3-years period for the ISO-9100 re-certification could be considered as an adequate period.

Comment to 2 Approval by the Competent Authority:
It is quite sure that the change of procedures for the implementation of such a system has to be treated as a significant change. But the present NPA does not offer guidelines regarding the approval process which has to be performed by

	the authorities. Which are the criteria for the approval of the changed system of supplier surveillance? Who is responsible for approving other-party surveillance systems that are not accredited by the „European co-operation for Accreditation“ (EA) on the basis of AS/EN 9100? Comment to 3 Conditions and criteria ... (3)(ii): What should be the basis for the POA holder to verify the appropriate qualification and sufficient knowledge of the other-party? Without performing audits or having the opportunity to inspect the qualification programs and the personnel records of the other-parties this verification can hardly be given. What are the means the authority can use to verify the POA holder's results? The direct access to the other-party's records by the authorities basically can be deduced from the POA holder's obligation in accordance with Part-21. But the right to perform surveillance of the other-party by the POA holder and the authorities should be noted. Comment to 3(3)(iii): The question regarding the frequency of surveillance activities has already been asked. The authorities should have the right to affect number and intensity of the surveillance activities. If the other-party systems participate in a certification scheme in compliance with AS/EN 9100 and apply the three-year period which represents a common standard at present the question raises how to deal with potential changes of the re-certification periods of the AS/EN 9100. Comment to the paragraph following 3(3)(vii): The term „based on the AS/EN 9100“ should be replaced by „in compliance with AS/EN 9100“. Which is the legal status of the instance „European co-operation for Accreditation“ (EA)? Is it a self-organisation of the other-party systems? By which means does this organisation make their results available to the public? Should it not be part of the function of the government's supervision to evaluate the qualification of the other-party? Due to the cross-state character of the industrial consortium the surveillance would fit into the broad spectrum of tasks of the EASA. Comment to 3(7)(c): Numbering inconsistent, „(d)“ should be correct.
response	*Partially accepted* Comment to 1 General, 2nd paragraph. This paragraph provides a description of the typical characteristics of an industry controlled certification system. "Appropriately recognised or accredited" refers to systems where a supplier is certified by an industry system. This is not within the remit of the Basic regulation and also not within the scope of this rulemaking task. This NPA does not propose to extend the scope of the Basic Regulation to other parties like Certification bodies. Comment to 1 General, 2nd paragraph, last sentence. This is also part of the description of what such an industry controlled certification should contain. It is not a requirement of that system because that is regulated by the Basic Regulation.

Comment to 2 Approval by the Competent Authority.
The criteria to be used for the assessment of the change of the POA's method of vendor and sub-contractor assessment, audit and control are provided in paragraph 3 of this AMC.
Other-party surveillance systems are NOT approved because these systems are not within the scope of the Basic regulation. These systems are typically used across various area of industry. (Automotive, chemical etc.) It is not intended to approve these systems.

Comment to 3 Conditions and criteria...(3)(ii)
The basis for the POA holder to verify if the other party is suited to perform their task would be to check if the other party would perform the task equal or better to the POA himself. The criteria listed in (3) are the area that should be considered.

Comment to 3(3)(iii)
There is truth in this statement. If the frequency of surveillance activities from an industry system is too low compared to the control that the POA holder would require; such a task would not be carried out equal or better than performed by the POA holder himself.
However, there are no requirements with regards to the frequency of vendor and subcontractor assessment and control (21A.139(b)(1)(ii)).
Frequencies in the requirements are stated in 21B.235(c), and relate to the approval of the production organisation. For example; in the extreme case when there would be a 100% incoming inspection applied to parts from a supplier, it could be that there is no vendor assessment audit and control.

Comment to the paragraph following 3(3)(vii)
Not accepted. The text is however amended to more clearly reflect that verification of the specified conditions is deemed to be met when the OP is an accredited signatory of the Multilateral Agreement with EA for the scope of their oversight. More information regarding the status and relation between EA, national accreditation boards and the European commission can be found on the website www.european-accreditation.org and in Regulation (EC) No 765/2008 of the European Parliament and Counsel of 9 July 2008.

Comment to 3(7)(c)
Accepted

comment *22* comment by: *UK CAA*

Page 15, Paragraph No: AMC No 2 to 21.A.139(b)(1)(ii)

Comment: It is not immediately clear what the difference is between AMC No 1 to 21.A.139(b)(1)(ii) and AMC No 2 to 21.A.139(b)(1)(ii). From the preamble detailed in paragraph 13 on page 6, in AMC No 1, the other party does not hold any form of certification and in AMC No 2 they do. However it would appear from the proposed text to AMC No 2 that very little credit is being given to the fact that the organisation holds any form of certification.

response *Noted*

The difference between AMC No. 1 and AMC No. 2 is not certification of the other party. The difference is the direct link (contract) between the POA holder and the other party in AMC No. 1 where there is no direct link between both in

AMC No. 2.
As stated in the preamble, the AMC No. 1 is true "outsourcing" of work by the POA holder.
AMC No. 2 are the criteria used for verification that the oversight by such an other party scheme, resulting in a suppliers certificate, can be used to substitute the assessment, audit and control of the POA holder.

comment *23* comment by: *UK CAA*

Page 15, Paragraph No: AMC No 2 to 21.A.139(b)(1)(ii) para 1

Comment: The use of suppliers holding some form of certification may be on a global basis and are likely to be used by a number of POA holders based in different EU Member States, which in turn are required by 21.A.157 to allow competent authorities based in different EU member states to carry out investigations. There is potential for these organisations to be subject to various standards and interpretations of the regulations.

In order to reduce the variation in standards the guidance material should contain details of which certification bodies or standards are considered acceptable. It is suggested that where suppliers hold certification such as EN9100 (as stated on page 6), the certification organisation is subject to a single assessment from EASA or another appointed Member State that can be recognised by all other Member States.

It is proposed that EASA only accepts appropriate aerospace certification standards.

Justification: To enable a consistent standard to be applied.

Proposed Text: 'The use of suppliers that are certified by another party in accordance with this AMC and recognised by EASA, should be part of the production organisation quality system'.

response *Not accepted*

The proposed text change is not accepted. However, the comment is true that duplication of oversight activities by Competent Authorities is potentially possible. GM No. 1 to 21B.220(c) however already identifies the need for liaison arrangements between competent authorities.
Recognition of certification organisations is not proposed within the AMC because these organisations exist in various natures and not limited to aviation only. The Competent Authorities need to develop tools to share experience that are flexible enough to follow developments in the certification organisations and the applied standards. This is however not in the scope of this rulemaking task.

comment *26* comment by: *Embraer - Indústria Brasileira de Aeronáutica - S.A.*

AMC No. 2, Paragraph 3(c)(1)—It is not clear to us whether the intent of this paragraph is that the actual procedures specify by name(s) the other parties that have certified suppliers, or that the procedures specify a requirement to maintain this information inside the approved quality system.

Embraer believes that it should not be necessary to amend the procedures each time a new supplier is qualified using another party, but that the

identification of the other party is an essential element to maintaining supplier control. This would be best implemented by revising paragraph 3(c)(1) to be similar to 3(c)(2):

(1) Listing ~~Identification~~ of the other party that has certified or will certify suppliers and will conduct supplier assessment and surveillance or the scheme under which the accreditation of the other party is controlled. This listing shall be maintained by the POA holder and made available to the Competent Authority upon request.

response *Accepted*

This paragraph (1) requires to specify who (the identification of the certification body) or the industry system that is controlling this supplier certification.
The proposed text is accepted.

comment *34* comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
AMC No 2 to 21A.139(b)(1)(ii)
Paragraph §1 : sentence "The assessment and surveillance of suppliers is considered to be adequately carried out when the conditions of this AMC are fulfilled."

2. COMMENT:
This use of other party suppliers certification is not sufficient to demonstrate the control of suppliers. Particularly it can not cover all the techniques listed in GM No 2 to 21A.139(a).

response *Accepted*

The AMC is specific to 21A.139(b)(1)(**ii**) because other aspects of the supplier control, like 21A.139(b)(**iii**) remain separately applicable and are not complied with by the use of this AMC.

comment *35* comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
AMC No 2 to 21A.139(b)(1)(ii)
Paragraph §3(c)(3)(iii)

2. COMMENT:
This frequency of verifications and audits is included in certains standard (such as with ISO 9100). In those instances, the POA holder has no possibility to influence the other party surveillance frequency and therefore, the referenced **§3(c)(3)(iii)** is impossible to achieve.

response *Noted*

If the frequency of surveillance activities from an industry system is too low compared to the control that the POA holder would require; such a task would not be carried out equal or better than performed by the POA holder himself.
However, there are no requirements with regards to the frequency of vendor and subcontractor assessment and control (21A.139(b)(1)(ii).

comment 36 comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
AMC No 2 to 21A.139(b)(1)(ii)
Paragraph §3(c)(3)(v) and §3(c)(6)

2. COMMENT:
In actual ICOP scheme (ISO 9100), the access to the surveillance report and non conformities included in the data base is restricted to organisations authorised by the supplier. Suppliers considers data as private and are reluctant to give access to "**detailed**" information

response *Noted*

In order to rely on oversight by another party, the POA holder has to be able to get access to audit information. It should be acceptable for a supplier that is delivering items to the POA holder to give access to this information. If access to this information is denied by the supplier, the criteria of this AMC can not be fulfilled

comment 37 comment by: *Claude Mas*

1. AFFECTED PARAGRAPH:
AMC No 2 to 21A.139(b)(1)(ii)
Paragraph §3(d) (The second (c) as numerotation is wrong in the NPA.)

2. QUESTION:
Has will the responsibility be shared between NAA and EASA in the evaluation of suppliers certification scheme? The evaluation will be necessary to keep confidence in the whole process.

response *Accepted*

The error will be corrected
Response to the question
The liaison between NAA's and the Agency needs to be established in order to exchange experience with OP.
The evaluation of supplier certification **schemes** is not a responsibility of the Agency or the NAA because this is outside the remit of the Basic Regulation. For the European accredited scheme the EU regulation 765/2008 defines the legal responsibilities.

comment 45 comment by: *Rolls-Royce plc [DGJ]*

§3

The term "supplier certification" is only loosely defined in this AMC, and its use in, for example, a Production Organisation Exposition might lead to some confusion. We would suggest the following amendments to clarify…

(a) The POA holder ~~needs to~~ shall include the use of ~~supplier certification~~ certificates of approval issued under an accredited system for supplier assessment and surveillance in the POA holder's quality system to demonstrate compliance with the applicable requirements of Part-21.

(b) Procedures required for use of ~~supplier certification~~ certificates of approval issued under an accredited system for supplier assessment and surveillance

~~need to~~ shall be consistent with other procedures of the POA holder's quality system.

(c) Procedures of the POA holder that uses ~~supplier certification~~ certificates of approval issued under an accredited system for supplier assessment and surveillance ~~need to~~ shall include the following:...

This eliminates potential ambiguity in the term "supplier certification" and aligns the text with paragraph 13 of the NPA. It pre-supposes that an "accredited" system is, by definition, "acceptable". It also reflects comment 38 regarding the use of "needs to".

response

Not accepted

The term "supplier certification" is loosely defined because it describes in general terms the characteristics of systems used by industry.
The proposed change is not accepted because it changes the intent from using a system to accepting certificates of approval. These certificates in themselves are not considered sufficient.

comment

46 comment by: *Rolls-Royce plc [DGJ]*

§3(c)(2)

This requirement is very broad and should be constrained…

"(2) A listing of ~~certified~~ those suppliers to the POA-holder which have been certified and are under surveillance by ~~the other~~ a third party…"

Justification: A third party may certify many suppliers, only a sub-set of which might be used by the POA-holder. As written, the text would suggest that the whole list of certified suppliers would have to be declared, which is both unnecessary and potentially burdensome to maintain. The suggested amendment also reflects comment 39 regarding the use of "other party".

response

Partially accepted

The text will be changed to show that only those suppliers need to be listed that are under surveillance by the other party and used by the POA holder.

comment

47 comment by: *Rolls-Royce plc [DGJ]*

Editorial suggestions for clarity

§1

"The assessment and surveillance of suppliers by a third party shall be deemed to satisfy the requirements of 21A.139(b)(1)(ii) ~~is considered to be adequately carried out~~ when the conditions of this AMC are satisfied ~~fulfilled~~."

§3(c)

The words…

"The POA holder needs to have …"

…which begin sections (5), (6) and (7) are superfluous since the preamble

already states (including amendments suggested under comments 38 and 45) that…

"(c) Procedures of the POA holder that uses ~~supplier certification~~ certificates of approval issued under an accredited system for supplier assessment and surveillance ~~need to~~ shall include the following: ".

§3(c)

Typographical error – last subparagraph should be numbered "(d)" not "(c)" as shown.

response *Partially accepted*

The proposed changes to § 1 is partially accepted. Instead of third party, other party is kept.

The first comment to 3(c) is accepted.

The second comment to 3(c) is not accepted. Refer to comment 45.

The third comment to 3(c) (typographical error) is accepted.

comment *48* comment by: *Rolls-Royce plc [DGJ]*

§3(c)(5)

> "(5) The POA holder needs to have procedures that ensure the POA holder is aware of the loss of an existing certification"

…would be more clearly written as…

> "(5) ~~The POA holder needs to have procedures~~ Arrangements that ensure the POA holder is made immediately aware ~~of the loss of an~~ if the third party intends to revoke a supplier's existing certification".

We believe that the "intention" is important so that the POA-holder is given as much advanced warning as possible before the certification is removed, rather than being informed of something which may have occurred at some time in the (distant) past. The suggested amendment also reflects comment 39 regarding the use of "other party".

response *Not accepted*

The proposed change removes the obligation from the POA holder to a non defined entity. Also "intends to" is premature and can not be complied with.

comment *49* comment by: *Rolls-Royce plc [DGJ]*

It is noted that much of the text of AMC No.2 to 21A.139(b)(1)(ii) has been drawn from FAA Order 8120.12. This promotes US/EU harmonisation. However, it would help if the exact language of AMC No.1 were kept identical to that of AMC No. 2 wherever technically appropriate, to avoid possible misinterpretation. Two examples of inconsistency follow:

1. Are the differences between the following two texts intentional?

AMC No.1 to 21A.139(b)(1)(ii)

(iv) Verification that the suppliers' assessment and surveillance is conducted on-site by the other party.

AMC No.2 to 21A.139(b)(1)(ii)

(iv) Verification that the suppliers' surveillance was conducted on-site by the other party.

2. The language in the two AMCs differ and are not consistent with the regulation:

AMC No.1 to 21A.139(b)(1)(ii) §3(c)(5) refers to "non-conformances"

AMC No.2 to 21A.139(b)(1)(ii) §3(c)(6) & (7) refer to "nonconformities"

We presume that both are referring to the same effect, and that the issue being addressed concerns the non-conformances of a product to its drawing, rather than the supplier's lack of compliance with procedure. If so, we would suggest using the same words as used in 21A.139, ie "non conforming items".

We would recommend that a line-by-line comparison of the two AMCs be carried out to ensure consistency between the two.

response

Partially accepted

The FAA Order 8120.12 has been used as the basis for this AMC. It was however believed that the text was not clear enough on certain aspects. Therefore it was decided to split the two systems applied for oversight into separate AMC and amend the text for that purpose.

The identified difference between the two lines (iv) in both AMC is partially intentional. The initial assessment of a supplier is considered to be carried out by the POA holder. The past tense is corrected in AMC No. 2.

AMC No. 1 will be amended to say nonconformities. Both are however referring to lack of compliance with procedures. These AMC address the vendor and subcontractor assessment audit and control, not 21A.139(b)(1)(viii) Non conforming item control.

comment

50 comment by: *Rolls-Royce plc [DGJ]*

The items requiring verification, listed in §3(c)(3), do not make clear that the scope of any third party oversight must include those areas of the supplier's operation dealing specifically with the work of the particular POA-holder. It would be meaningless to claim credit for third party certification when such third party oversight related to a different aspect of the supplier's activity. The following amendment may clarify:

> (iv) Verification that the supplier's[1] surveillance was conducted on-site by the ~~other~~ third party and covers those aspects of the supplier's activity carried out on behalf of the POA holder.

The suggested amendment also reflects comment 39 regarding the use of "other party".

	A similar comment may be applied to the corresponding text in AMC No. 1 to 21A.139(b)(1)(ii).
response	*Partially accepted* It is agreed that it should be made clearer that the scope of the other party oversight should include those area that need to be covered for the POA holder. A change to paragraph 3(c)(3)(i) is proposed. (See resulting text).

resulting text

AMC No. 2 to 21A.139(b)(1)(ii)
Vendor and sub-contractor assessment, audit and control - Production Organisation Approval (POA) holder using other party supplier certification

1 General

Note

For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as "suppliers", regardless of whether or not they hold a POA and audit and control is hereafter referred to as "surveillance".

Other party supplier certification is a method whereby a supplier contracts with an appropriately recognised or accredited Other Party (OP) for the purpose of obtaining a certification from that OP. Certification indicates that the supplier has satisfactorily demonstrated to meet the applicable standard on a continuing basis. OP certification results in placing the supplier on the OP list of certified organisations, or in the supplier receiving a certificate identifying the requirements that have been met. Periodic follow-up evaluations are conducted by the OP to verify continued compliance with the requirements of the applicable standard.

The production organisation is required by Part-21 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The assessment and surveillance of suppliers by an OP should be deemed to satisfy the requirements of 21A.139(b)(1)(ii) when the conditions of this AMC are satisfied. The assessment and surveillance of suppliers by OP as part of supplier certification does not exempt the POA holder from its obligations under 21A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The use of suppliers that are certified by OP in accordance with this AMC should be part of a production organisation quality system.

2 Approval by the Competent Authority.

Implementing or changing procedures for using suppliers that are certified by an OP is a significant change to the quality system and requires approval in accordance with 21A.147.

3 Conditions and criteria for using supplier certification for the supplier assessment and surveillance.

(a) The POA holder should include the use of supplier certification for the supplier assessment and surveillance in the POA holder's quality system to

demonstrate compliance with the applicable requirements of Part-21.

(b) Procedures required for use of supplier certification for the supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.

(c) Procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:

(1) Listing of the OP that has certified or will certify suppliers and will conduct supplier assessment and surveillance or the scheme under which the accreditation of the OP is controlled. This listing should be maintained by the POA holder and made available to the Competent Authority upon request.

(2) A listing of the certified suppliers under surveillance by the OP and used by the POA holder. This listing should be maintained by the POA holder and made available to the Competent Authority upon request.

(3) The method used by the POA holder to evaluate and monitor the certification process of any OP certification body or OP certification scheme used. This applies not only to new suppliers, but also to any decision by the POA holder to rely on OP certification of current suppliers. The method should include the following as a minimum:

(i) Verification that certification standards and checklists are acceptable and applied to the applicable scope.
(ii) Verification that the OP is appropriately qualified and has sufficient knowledge, experience and training to perform its allocated tasks.
(iii) Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.
(iv) Verification that the suppliers' surveillance is conducted on-site by the OP.
(v) Verification that the surveillance report will be made available to the Competent Authority upon request.
(vi) Verification that the OP continues to be recognised or accredited.
(vii) Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers' functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the OP certification, the items (ii), (iv) and (v) shall be deemed to be complied with.

(4) A definition to what scope the OP will conduct suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.

(5) Procedures that ensure that the POA is aware of the loss of an existing certification.

(6) Procedures that ensure that the POA holder is aware of nonconformities and has access to detailed information of these nonconformities.

(7) Procedures to evaluate the consequences of nonconformities and take appropriate actions.

(d) The POA should make arrangements that allow the Competent Authority to make investigation in accordance with 21A.157 to include OP activities.