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MKO/gfe/FS.5  
Cologne,

Mr Alessandro Cardi  
ENAC – Italian Civil Aviation Authority  
Viale Castro Pretoria, 118  
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**Subject: Monitoring of Quality System**

**10. NOV. 2015**

Dear Mr Cardi,

Referring to your letter addressing the “Monitoring of Quality System”, we would like to provide you with the up-dated EASA position on assessment principles of the Compliance Monitoring System/ Quality Assurance System, which should clarify your main concerns.

Taking into consideration the applicable regulatory framework of the Compliance Monitoring System/ Quality Assurance System in different domains with the conclusion that all relevant Implementing Rules stipulate very comparable requirements, the following conclusions are applicable across all domains:

- Ensuring effectiveness of the Compliance Monitoring System / Quality Assurance System is the ultimate responsibility of the Accountable Manager of an approved organisation (operator, maintenance organisation, training organisation, service provider etc.).
- For execution of this responsibility adequate means of internal assessment shall be set-up and deployed, depending on the nature, size and complexity of the organisation, allowing necessary flexibility in selecting internal assessment method (e.g. a topic of the independent audit executed by internal or external auditor, an element of the management review, a topic of the individual Accountable Manager action etc.).
- It is the responsibility of a Compliance Monitoring Manager or Quality Assurance manager to demonstrate to the Accountable Manager that the organisation is working in compliance with the relevant standard(s)/regulation(s); this principle cannot be find appropriate for dealing with the activities they are directly responsible for (e.g. the activities related to the requirements as 21.A.139, 145.A.65, M.A.712, ORO.GEN.200, etc.), due to the evident “potential conflict of interests” (the person performing the internal assessment of the Compliance Monitoring System/Quality Assurance System must be independent).

- By introducing flexibility for the “internal assessment” of the Compliance Monitoring System/ Quality Assurance System, either by the independent internal or contracted auditor or by the activities in scope of the independent management review or by the other appropriate means, a possibility is given to an undertaking / organisation to design and tailor this activity according to its size and complexity (including small and simple organisations, where the Accountable Manager might be a sole person in charge).

It should be specifically emphasised that verification of the effectiveness of the Compliance Monitoring System/Quality Assurance System has to be already ensured inside the organisation by the appropriate internal assessment which should be based on principles allowing necessary flexibility. It should be considered that the Competent Authority activities represent a second independent layer of checking this topic and due to that cannot in any case represent an appropriate alternative to the “internal assessment”.

Hopefully this clarifies the need for an appropriate internal assessment of the Compliance Monitoring System/Quality Assurance System. Considering the Agency’s position, please be informed that your request to cancel the finding related to the “Monitoring of Quality Assurance System” (ref. No. 17491) cannot be accommodated.

In the case that further clarifications are needed, we remain at your disposal.

Yours sincerely,



Ricardo GÉNOVA GALVÁN