

FAQ n.20109**FAQs:**

Applications, Design Organisations

Question:

What are the expectations of the Agency in respect to the independent system monitoring of a DOA holder?

Answer:

First of all the Agency expects the Independent System Monitoring of a DOA Holder to:

- be properly placed within the Design Organisation in order to have the Independency ensured (above process owners and below the Head of Design Organisation);
- be properly staffed with persons having relevant Part-21 expertise and process monitoring (auditing) skills;
- have a feed-back system to person(s) having the responsibility to ensure corrective actions (such as process owner, DOA Management or Head of Design Organisation).

Independence means that the ISM staff should not be involved in the processes and produce deliverables of the processes but may:

- Support process owners in defining processes compliant with Part-21;
- Support process owners in the analysis of the root cause of the issues collected during process monitoring;
- Support process owners in defining corrective actions;
- Support process owners in verifying the effectiveness of the corrective actions;
- Liaise with the EASA DOATL;
- Report summarised information related to Design Assurance System performance / health to the Head of Design Organisation.

This function may:

- be subcontracted or,
- be performed by the Quality Organisation under some conditions mentioned in the presentation [Independent System Monitoring](#) on the EASA website.

The Agency considers that effective monitoring means to ensure:

- Compliance of the Handbook and procedures with Part-21;
- The adequacy of the procedure;
- Appropriate technical content of the deliverables;
- Process adherence (compliance with procedures);
- Monitoring and analysis at process level performed by competent staff;
- Systematic collection of issues arising during a given process (e.g. difficulties or good performances during change or STC process);
- Systematic and complete reporting about health of the process (performance and not only non-conformities).

For further details please refer to the presentation Independent System Monitoring.

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Link:

<https://www.easa.europa.eu/faq/20109>