

#	Question	Proposed Reply
1	How will the VORs be managed?	The Agency manages VORs in the same way as the MORs. The safety issue contained in the report is subject to investigation/analysis by the relevant EASA staff or relayed to the relevant authority. The Agency has a dedicated process to identify and manage reports received on the same occurrence. In the database, all reports related to the same occurrence are stored in a single record. However, the information is not mixed - the staff accessing to the record is able to distinguish each report and its content. This process, with minor changes, will be used to discharge EASA responsibilities in Regulation 376/2014.
	Which will be the feedback towards the Manufacturers?	In the cases of occurrences reported by Design Approval Holders related to the continuing airworthiness of their products, or by organisations approved by the Agency related to their organisation approval, the Agency provides in general feedback to those organisations through the direct discussion of the safety issue with the relevant staff in the Agency (PCM or Team Leader). The Agency plans to implement further improvements in the way it currently provides feedback on individual occurrences.
	How will VORs and MORs on the same event be "coupled" in the ECR?	The ECR is managed by the European Commission. On the general problem of duplicate reports for a single occurrence, the European Commission launched a study with some MS, the Joint Research Centre and EASA, to define a technical proposal to handle reports related to the same occurrence in the ECR. The proposal was submitted and approved by the ECCAIRS Steering Committee (body governing the development of the software used in the ECR, MS and EASA for storing occurrence records) and its technical feasibility is now to be assessed. The proposal is based on four steps (identification, linking, tagging and integration) in order to facilitate the analysts accessing to the ECR by providing a full view of each event (all records received on each occurrence) but at the same time to support more accurate trend monitoring (counting only once each occurrence, and not as many times as reports related to that occurrence were received in the ECR).
2	The Rule needs a monitoring of the implementation of the Corrective Actions in service. What can a Manufacturer do when the Customers often don't provide any feedback to the Company?	Manufacturers are required to put in place to a process to monitor the implementation of the corrective action. However, it is recognized that manufacturers do not have the means to enforce such corrective actions and should not be held responsible for the action or lack of action from organisations independent of their own organisation.
	Shall the Manufacturers be responsible for this implementation?	Manufacturers are required to put in place to a process to monitor the implementation of the corrective action. They shall ensure that their customers are informed about the need to implement the Corrective Actions.

		<p>However, it is recognized that manufacturers do not have the means to enforce such corrective actions and should not be held responsible for the action or lack of action from organisations independent of their own organisation.</p>
<p>3</p>	<p>Part 21 is supposed to be modified in the near future to accommodate requirements for SMS in design and manufacturing published in ICAO Annex 19. Should we expect some interactions between these future changes and the reporting requirements resulting from both 216/2008 and 376/2014 regulations?</p>	<p>It is the intention of the Agency to review reporting requirements in the Implementing Rules of BR 216/in view of the new Regulation 376/2014 to ensure consistency of European legislation. Reporting requirements (e.g., reporting between organisations) not covered by Regulation 376/2014 will remain and will be developed as necessary. Development of SMS-related requirements in the Implementing Rules of Basic Regulation 216/2008 will also take into consideration the requirements laid down in Regulation 376/2014. The rulemaking tasks dealing with SMS are being reviewed to accommodate the necessary changes in light of Regulation 376/2014. Future rulemaking tasks will, in the same way, consider Regulation 376/2014 as part of the Terms of Reference.</p>
<p>4</p>	<p>How voluntary reporting and culture fit together. Implementing the "voluntary reporting" provisions of Regulation 376/2014 could create a climate of mistrust if it misused by people not willing to discuss occurrences openly. Do you share our perception that "anybody reporting anything" has the potential to create mistrust in organisations of any form and any kind?</p>	<p>Voluntary reporting does not mean anonymous reporting. Voluntary reporting is meant to promote reporting of occurrence or other safety related information not covered by the mandatory reporting. Voluntary reporting is offered the same strong level of protection and the same level of vulnerability than the mandatory reporting.</p> <p>In the European regulatory framework, VORs were already part of Directive 2003/42/EC on occurrence reporting in civil aviation.</p>
<p>5</p>	<p>Examples of how the IORs improved safety could not be presented;</p>	<p>IORs is the internal system put in place by the Agency to centralize the processing of occurrences reported to the Agency ensuring traceability in a closed-loop system. As such, IORS main goal is to support the Agency's responsibilities for the Continuing Airworthiness of certified products and for the organisation oversight and Standardisation of MS in a second extension. It allocates reports to EASA experts/PCM within their remit and trace assessment and potential corrective actions (Mandatory or non-Mandatory Continued Airworthiness Information publication for instance). Safety Improvements are brought by the safety actions taken by the Agency in response to occurrence data and other data. For example, most of the ADs and Safety Information Bulletins issued by the Agency originates from occurrence data.</p>

	In addition to this, the Agency is currently reviewing its analysis activities in order to do better use of IORS data for trend monitoring and identification of safety issues in compliance with Regulation 376/2014.
6	<p>I would have liked a more developed answer to my question about follow-up reporting (Art 13). It was acknowledged that the timescales prescribed in 376/2014 aim to cater for the various types of reporting organisations and recognised that investigations carried out by TC Holders usually require more time to complete. Please can EASA ensure that, in this respect, the forthcoming guidelines clearly reflect its expectations?</p> <p>The regulation states that for those occurrences where additional analysis is needed, organisations shall report a follow-up of the analysis to the competent authority in 30 days after submitting the initial one, and the final results, in principle, 3 months after that initial submission. It is acknowledged, and in this way it will be reflected in the guidelines, that there are cases for which three months will be not enough time to provide the final results. Final results reported after a period longer than the encouraged 3 months period are not infringing the EU Regulation.</p>
7	<p>Art 6, item 1 In what manner does the person need to handle details of occurrence reports “independently”? Please clarify;</p> <p>The interpretation of “independently” will be clarified in the Guidelines Document to be issued by the European Commission in April/May 2015. While a separation between the departments handling occurrence reports and the rest of the organisation may be considered as a way to achieve this objective, it is not required as such by the Regulation. Therefore organisations have flexibility in the way they are organising themselves with the view to achieve the Just Culture objectives.</p>
8	<p>As a non-Member State there should be an item in the agenda to clarify the EASA requirements for NON Member states, too. I had a chance to talk with some EASA personnel to clarify some questions;</p> <p>Organisations approved in non-Member States are not subject to Regulation 376/2014. However, relevant reporting requirements relating to their approval under the Basic Regulation 216/2008 and its implementing rules (including AMC and GM) remains applicable, unless stated differently in a BASA with that State.</p>
9	<p>A clarification might be made between the new regulation R376-2014 and R216/2008 for those non-Member States organizations;</p> <p>Organisations approved in non-Member States are not subject to Regulation 376/2014. However, relevant reporting requirements relating to their approval under the Basic Regulation 216/2008 and its implementing rules (including AMC and GM) remains applicable, unless stated differently in a BASA with that State.</p>

<p>10 A clear view on how EASA wants to use the IORS database for statistics, trends and detection of safety issues was missing;</p>	<p>The Agency is currently reviewing its analysis activities in order to do better use of IORS data for trend monitoring and identification of safety issues in compliance with Regulation 376/2014.</p>
<p>11 I look forward to seeing which "voluntary" occurrences EASA is waiting to be submitted. I struggled to understand this aspect of the presentation;</p>	<p>The requirement to implement a voluntary reporting system in the Agency and MS is aligned with States international obligations under Annex 19. Its objective is to give the possibility for aviation professionals to report occurrences and other safety related information not falling under the mandatory scheme.</p>
<p>12 Data sharing: this should only be possible between EASA, authorities and investigation bodies. On the other hand, approved organisations (CAMO's, AMO's and in future DOA's) shall implement a SMS with hazard identification and risk assessment. I see a great problem regarding risk assessment of hazards without the availability of industry data, especially the calculation of risk probability. Can you please provide guidance, how risk assessment should be accomplished without industry data?</p>	<p>The content of the ECR is indeed limited to entity entrusted with regulating civil aviation safety and investigation bodies in the EU. Any interested party defined in the Regulation can request access to information (aggregated or anonymised) from the European Central Repository. Some necessary requirements are to be met as detailed in the articles 10 and 11 of Regulation 376/2014 as well as in Annexes II and III. These interested parties can have more detailed information on occurrences related to their own equipment (product), operations or field of activity. This provision should facilitate the availability of safety related data to carry out required assessments.</p>

<p>13 Regulation 376/2014 is not applicable for approved organizations at non-MS although reporting is mandatory for all POA and DOA as per 748/2012 (MOA should also be considered for Non-MS). The subject should be clarified to prevent misunderstanding situations. Because non MS approved organizations shall perform reporting i.a.w. applicable regulations (748/2012). In addition to this, is 216/2008 applicable for non-MS organizations approved by EASA (POA/MOA/DOA)?</p>	<p>Regulation 376/2014 does not repeal or amend any requirement in the Basic Regulation 216/2008 and its implementing rules. That means that both regulatory frameworks remain valid and applicable to organisations, Member States and the Agency. For organisations approved out of the MS, the requirements to maintain their approval are the ones applicable.</p> <p>Organisations approved in non-Member States are not subject to Regulation 376/2014. However, relevant reporting requirements relating to their approval under the Basic Regulation 216/2008 and its implementing rules (including AMC and GM) remains applicable, unless stated differently in a BASA with that State.</p> <p>The Guidelines Document to be published by the European Commission will clarify this again.</p>
<p>Reporting between the organizations, NAAs, EASA should be clarified/detailed based on approval holder status (i.e. MOA, POA, DOA);</p>	<p>Regulation 376/2014 does not repeal or amend any requirement in the Basic Regulation 216/2008 and its implementing rules. Therefore, both regulatory frameworks remain valid and applicable to organisations, Member States and the Agency. Although both frameworks are compatible, it is noted that clarifications on certain aspects are needed. The Guidelines Document to be published by the European Commission aims at, among other goals, providing clarifications on the interaction between Regulation 376/2014 and reporting requirements in Basic Regulation 216/2008 and its IRs.</p>
<p>14 What happens after reporting an occurrence, i.e. is there any feedback from EASA about actions, status, etc., to the reporting organisation foreseen or will this be visible in the ECR?</p>	<p>All occurrences received in the Agency are subject to individual review. Occurrences requiring further assessment are allocated to the relevant technical staff in the Agency and followed up until closure.</p> <p>Regarding the feedback to the reporting organisation, in the cases of occurrences reported by Design Approval Holders related to the continuous airworthiness of their products, or by organisations approved by the Agency related to their approval, the Agency provides feedback to those organisations by the direct discussion with the relevant staff in the Agency (PCM or Team Leader). The Agency also provides a quarterly feed-back to National Aviation Authorities on their reporting.</p> <p>The ECR will contain the resolution of the occurrences as stated by the Member State or the Agency, but this information will not be directly accessible to any reporting organisation or individual.</p>

<p>15 Which interfaces and processes between EASA and Industry are foreseen for each single occurrence?</p>	<p>Regulation 376/2014 does not change current responsibilities of organisation or the Agency as established in Basic Regulation 216/2008 and its implementing rules. This means that each occurrence will be subject to the same process applicable today, either for the continuing airworthiness of certified products or for organisation oversight. In these two cases, organisations and EASA staff interacts as per existing processes (i.e., continuing airworthiness review meetings, organisation surveillance visits, etc.).</p>
<p>Will this be more detailed stipulated in the guidance material?</p>	<p>In the scope of the remits of the Agency, the interfaces between the industry and the Agency are not foreseen to be developed further in the Guidelines Document.</p>
<p>16 Have all occurrences to be reported even if originated by hazard and/or without having verified cause and/or safety impact due to lack of information or missing suspected part and appliance for further investigations from operations?</p>	<p>In the case of mandatory reporting, all occurrences listed in the coming Implementing Rule of Regulation 376/2014 shall be reported. For other occurrences, then falling under the voluntary reporting, they shall be reported by the organisation to the authority once the potential safety impact has been confirmed. That means that for the organisation, the reporting to the authority of those occurrences captured in the voluntary system shall be mandatory in those cases where their assessment has resulted in the confirmation of the potential safety impact.</p>