

	<p><b>Aeronautical Services</b></p> <p><b>Advisory Memorandum</b></p> <p><b>(ASAM)</b></p> <p><b>Focal Point: ANSP</b></p>	<p><b>ASAM</b></p> <p><b>No: 43</b></p> <p><b>Issue 2.0</b></p> <p><b>Date 22.11.2024</b></p>
<b>Title</b>	<b>Advisory on a ‘Comment Response Document’ used by the Competent Authority to provide regulatory feedback to Service Providers</b>	

**1. Introduction**

This material outlines the structure and use of a regulatory form OPS.ANS.F.257 ‘Comment Response Document’ (CRD) which is used by the competent authority (CA) to provide regulatory reviews to ATM/ANS service providers (SPs).

**1.1. Scope**

This ASAM applies to all SPs certified by the Irish CA in accordance with the regulatory requirements of Commission Regulation (EU) 2017/373.

The CRD document has universal use and is intended to record CA comments corresponding to its regulatory oversight review activities, which are performed on document(s) provided by a SP in their various submissions to the CA e.g.

- Changes to the functional system,
- Approval of change management procedures for functional systems
- Changes to the provision of service,
- Changes to the management system,
- Changes to the safety management system, that does not affect the functional system, and/or
- other areas as determined.

**1.2. Responsible Person**

The ANSD of the Irish Aviation Authority (IAA) is the CA for Ireland in respect to Regulation (EU) 2018/1139, and Commission Implementing Regulation (EU) 2017/373.

The Manager, Air Navigation Services Division (ANSD) of IAA has overall responsibility for this advisory material.

**2. References**

- Regulation (EU) No. 2018/1139.
- Commission Regulation (EU) 2017/373.
- ASAM No. 38.
- ASAM No. 39.

### 3. **Structure of the CRD Document** (see template at appendix A)

The first 3 pages are used to record supplementary information, as outlined hereafter, with the fourth and subsequent pages containing a 'Comment Response Table' where CA comments with SP responses are recorded.

The supplementary information, to provide a record and traceability, will include details such as:

**Page 1;** the change title; name of the CA review person or team; name of the person who compiled the document; a 'CA – Comment Response Document History' table; a 'CA - Reviewed Documents' table which lists the documents which have been reviewed, with a record of their issue/version date and the dates they were submitted i.e. reception date.

**Page 2;** provides general information such as the comment remark's classification scheme; guidance on decision to stop a review and a 'CRD Comments Status Table' which outlines the amount of open comments and their status e.g. Major 3/ Minor 2 /questions 4. The use of this table is at the discretion of the review team/inspector. It is foreseen that it will not be used for small reviews or non-complex changes but more likely for complex or large/major SP changes where iterations of the CRD go back and forth.

**Page 3;** is for SP traceability and record keeping. The SP will, much like the CA on page 1, record information such as who contributed, who consolidated the responses etc and includes an 'SP - Comment Response Document History' table. This table includes a column for endorsement by a person with SP organisational responsibility who verifies the SP responses have been reviewed and are suitable for regulatory review. This person also ensures the SP information on page 3 of the CRD is accurate and complete.

**Page 4 onwards;** contains the 'Comment Response Table' where CA comments and comment classifications are recorded. Each comment is identified by an R number, the document name which is given an acronym and the section/ paragraph or page number within that document the CA comment refers to. The comments are classified according to the following 4 categories:

- **Major:** A comment on a critical issue ANSD considers significant enough to prevent regulatory approval of the proposed change(s) unless resolved by the service provider (e.g. a non-conformity to applicable regulatory requirements, or non-adherence to an organisation's own requirement, or an important problem that shall be resolved by the organisation).
- **Minor:** A comment on other issues indirectly affecting the compliance demonstration, which ANSD considers are necessary to address before proceeding. Whilst not solely preventing regulatory approval of the proposed change(s) the accumulation of these issues can lead to the prevention of regulatory approval of the proposed change(s).
- **Question:** The question may be associated to an issue that requires clarification. However, upon receipt of further information the CRD question classification will change to a Closed, Minor or Major classification.
- **Editorial:** Observations on missing information or editorials of a nature which are needed to provide clarity or ensure no ambiguity exists by the absence of that information.

The table also contains a column titled 'SP response'. This is where the SP will provide a response to each comment raised by the CA. Lastly there is a status column which is chosen and updated by the CA. The status of a comment can be one of the following:

- **Open:** For a new comment, or when a response is not yet considered satisfactory by the review team.
- **Dispositioned:** When an action is agreed.
- **Closed:** When the service provider provides a satisfactory written response, or when evidences are provided that an agreed action has been performed.

#### **Important to note**

Comments may be reclassified because of answers given or changes made by the SP during a review process. Also, the first or subsequent CRD review should not be seen as the complete extent of a review in terms of the number of comments. More comments can be added following a review where an issue was not picked up on previously or because the answer given by the SP warrants a further separate CA comment to the one initially raised.

#### **4. Use of the CRD**

When the SP sends notification of an intended change in general or to their functional system, the CA under its processes, may decide to conduct a review of that change.

For the CA decision to conduct a review of a notified change to the functional system see ASAM No. 38 and for other changes see ASAM No 39.

The following is the general methodology for the use of the CRD irrespective of the type of change.

Where the CA decides to conduct a review, it will notify the SP.

If no issues are found, the CA will close its review and inform the SP. The CA will retain the CRD document, which contains the supplementary information, as evidence of a review having been opened. Where it is a change to the functional system, the CA will issue an approval letter. The SP can implement the change as notified.

If issues are found the CA will forward a CRD. The SP shall address matters outlined in the CRD, and where it involves a change, get them resolved in a timeframe before operational ('O') date.

If all matters within the open CRD are resolved, the CA will close its review and inform the SP. Where it is a change to the functional system, the CA will issue an approval letter outlining any conditions or limitations.

If the SP response to a CA raised CRD is not sufficient to close the review the CA may

- (1) continue the CRD process back and forth until all matters are closed, or
- (2) suspend the review (see section 5).

Obviously if (1) or (2) above occur it may affect the 'O' date and the SP should plan accordingly.

For each iteration of a CRD the SP shall address the CRD comments and demonstrate that it has carried out a full evaluation\* to ensure no other issues are contained within its submission that could affect the regulatory approval letter being issued.

\*Note - Updated documents with a record of the chapters reviewed, the changes made to each and the name of the person who carried out the review, is one way the SP can declare demonstrates evidence that a full evaluation was carried out.

If matters are not being resolved to the CAs satisfaction e.g. a third CRD review is suspended, then the CA may stop its review altogether and issue a rejection letter. The change as proposed shall not go ahead.

**5. Suspension of a CRD review**

If the CRD review reaches the threshold numbers outlined below, the CA may suspend its review and send back the CRD. The decision to do this is predicated on how far into a review the threshold numbers are reached. The earlier the numbers are reached, especially for a large or complex change, the more likely the review will be suspended. This is on the understanding that enough issues have been identified that demonstrates the submission is not ready for regulatory approval and warrants being readdressed by the SP.

However, the review team/inspector may not stop the review if it is obviously more expedient to continue, for example, a document is short in length or most of a submission is compliant, i.e. correct, and complete.

CRDs may not extend to more than the following amount of open classifications before being addressed by the SP.

3 major or

2 major and 3 minor or

6 minor.

It is incumbent on a SP to ensure that material submitted for regulatory approval is at a minimum safety, compliance and quality checked before being submitted.

The CA may prescribe conditions under which the service provider may operate during such changes, which may include allowing the organisation to make a partial change whilst the regulatory review is ongoing.

**6. Further Information**

Any queries or requests for further information should be addressed to the following CA email address: [ansdinfo@iaa.ie](mailto:ansdinfo@iaa.ie)