



**COMMENT RESPONSE DOCUMENT (CRD)
TO NOTICE OF PROPOSED AMENDMENT (NPA) 2009-02e**

**for an Agency Opinion on a Commission Regulation establishing the Implementing
Rules for the medical fitness of cabin crew**

and

**a draft Decision of the Executive Director of the European Aviation Safety Agency on
Acceptable Means of Compliance and Guidance Material on the medical fitness of
cabin crew**

“Implementing Rules for Medical Fitness of Cabin Crew”

CRD a. 2 – Explanatory Note B

Explanatory Note B

I. General

1. The purpose of NPA 2009-02, dated 30 January 2009, was to develop an Opinion on the Implementing Rules for Air Operations of EU Operators and a Decision on the related Acceptable Means of Compliance (AMC) and Guidance material (GM). The scope of this rulemaking activity was outlined in Terms of Reference (ToR) OPS.001¹ and was described in detail in the NPA.
2. NPA 2009-02 was divided into 7 separate documents:
 - a. NPA 2009-02a containing the Explanatory Note and its Appendices;
 - b. NPA 2009-02b containing the Draft Opinion and Decision for Part-OPS;
 - c. NPA 2000-02c containing the Draft Opinion and Decision for Part-OR (Subpart OPS);
 - d. NPA 2000-02d containing the Draft Opinion and Decision for Part-AR (Subparts GEN, OPS and CC);
 - e. NPA 2000-02e containing the Draft Opinion and Decision for Part-CC and the Supplement to Draft Opinion Part-MED;
 - f. NPA 2000-02f containing the Cross-Reference Tables between EU-OPS, JAR-OPS 3 and the proposals presented in the NPA;
 - g. NPA 2000-02g containing the Regulatory Impact Assessment (RIA).
3. NPA 2009-02e, contained 2 draft proposals for Implementing Rules (IR) and related AMC and GM for cabin crew involved in operations of aircraft referred to in Article 4(1)(b) and (c) of Regulation (EC) No 216/2008 ('the Basic Regulation').
 - Draft proposals for the cabin crew attestation referred to in Article 8 (4) and 8 (5)(e) (Part-CC); and
 - Draft proposals for the medical fitness of cabin crew (Supplement to Part-MED comprising a new Section 4 'Medical fitness of cabin crew' to Subpart A 'General requirements' of Part-MED published in NPA 2008-17c, and Subpart E 'Requirements for medical fitness of cabin crew'.
4. The Supplement to Part-MED on medical fitness of cabin crew is the subject of this Explanatory Note B.

II. Consultation

5. NPA 2009-02 was published on the website (<http://www.easa.europa.eu>) on 30 January 2009.

The consultation period of the NPA was extended in accordance with Article 6(6) of the Rulemaking Procedure² at the request of stakeholders to ensure overlap with related NPAs and to provide more time for comments taking into account the size and scope of the NPA.

¹ NPA 2009-02 on Implementing Rules for Air Operations of EU Operators
[http://www.easa.europa.eu/ws_prod/r/doc/final%20ToR%20OPS.001%20\(20.07.06\).pdf](http://www.easa.europa.eu/ws_prod/r/doc/final%20ToR%20OPS.001%20(20.07.06).pdf).

² EASA Management Board Decision 08-2007, amending and replacing the Rulemaking Procedure, adopted at the Management Board meeting 03-2007 of 13 June 2007
(http://www.easa.eu.int/ws_prod/g/management-board-decisions-and-minutes.php).

By 31 July 2009³, the closing date of the consultation period, the European Aviation Safety Agency ('the Agency') had received 13.770 comments from over 417 commentators, including National Aviation Authorities, professional organisations, private companies and individual persons.

4. Due to the amount of comments received, and in accordance with the work programme established by the Agency in agreement with the European Commission and the Management Board, it was decided that the Comment Response Document (CRD) for NPA 2008-17 as well as for NPA 2009-02 would be divided and published in phases. Accordingly, the present CRD only focuses on NPA 2008-17c (Part-Medical) and NPA 2009-02e (Supplement to Part-Medical). An overview of the comments received to the latter, as well as of the changes made to the text of the NPA as a result, is included in Annex II to this Explanatory Note B.
5. The CRD for NPA 2009-02a to 02d and 02g will be published at a later stage in consecutive phases in accordance with MB 03/2009 approval of the European Commission and EASA joint approach on 'Rulemaking in the context of the extension of Community competences'⁴.

III. Publication of the CRD

6. The comment period for NPA 2008-17c closed considerably earlier than the one on NPA 2009-02e. The comments were treated differently. Following the MB 03/2009 referred to in paragraph 5, a decision was taken to apply the new working procedure for the comment review of NPA 2009-02e and to publish the provisions for the medical fitness of pilots (NPA 2008-17c) and of cabin crew (NPA 2009-02e) combined in this CRD as they will be for the Opinion and Decision on Part Medical.
7. The new working method applied for the comment review of NPA 2009-02e on medical fitness of cabin crew included the preparation, for publication in the CRD, of the following documents:
 - a. the list of comments received (CRD c.3);
 - b. a Comment Response Summary Table (CRD c.4) containing
 - the summaries of comments and the Agency responses,
 - the references to the BR, EU-OPS, adopted JARs and ICAO Standards,
 - the resulting changes to the NPA proposals for implementing rules; and
 - c. a clean version of the resulting text (CRD b.2 containing IRs of Subpart E and in CRD b.3 containing the related AMC/GM).
8. The Agency submitted the outcome of the comment review and the draft resulting text by written procedure to the Subgroup Medical to the FCL.001 review group⁵ as well as to the

³ In accordance with article 6.6 of the Management Board decision 08-2007, the Agency extended the consultation period for an additional period of 2 months to ensure overlap with related NPAs (from 30/05/2009 to 31/07/2009).

⁴ EASA Management Board 03/2009, of 15 September 2009, Agenda Item 6 (http://easa.europa.eu/ws_prod/g/doc/pr/PRen15092009.html).

⁵ Rulemaking group composition FCL.001 ([http://www.easa.europa.eu/ws_prod/r/doc/NPA/Review%20Group/Review%20Group%20Composition%20to%20NPA%202008-17%20\(FCL%20001.pdf\)](http://www.easa.europa.eu/ws_prod/r/doc/NPA/Review%20Group/Review%20Group%20Composition%20to%20NPA%202008-17%20(FCL%20001.pdf))).

OPS.001 review groups for Commercial Air Transport (CAT)⁶ and for non-commercial operations with complex motor-powered aircraft (NCC)⁷.

9. The said groups were created in accordance with the Rulemaking Procedure, and included the members of both the FCL.001 and OPS.001 core drafting groups as well as other experts from the Agency, National Aviation Authorities and industry, who had not been involved in the initial drafting phase.
10. The work on the review of comments was framed by the common approach to the extension of EU competences agreed between the Agency, the European Commission and the Management Board of the Agency. This common approach established not only a detailed prioritisation of the work to be developed by the Agency, but also high level principles that would preside over the review of the comments. Among these were the adherence to ICAO Standards and Recommended practices, EU law and adopted Joint Aviation Requirements (JARs); the necessity to give due consideration to safety and regulatory principles and to the current distribution of the text between hard and soft law, as well as to constraints such as changes stemming from the Basic Regulation and from Joint Aviation Authorities' (JAA) NPAs which had reached consensus; the need to create proportionate requirements; and, finally, the requirement to pay special attention to the clarity, legal certainty and enforceability of the proposed regulatory text.
11. In summarising the comments and preparing the responses, a classification has been applied to attest the Agency's acceptance of the comments. This classification is used in the Comment Response Summary Table as follows:
 - '1' for 'Agreed/Partially agreed' – Either the comment is agreed and transferred to the revised text, or the comment is only agreed in part by the Agency, or agreed but only partially transferred to the revised text.
 - '2' for 'Noted' – The comment is acknowledged by the Agency but no change to the existing text is considered necessary. Taking into account the high number of repeated comments, the classification '2' was also used for the repeated comments, the number and the source of which have been reported in the Comment Response Summary Table (CRD c.4).
 - '3' for 'Conflict with Regulation (EC) No 216/2008/Not Accepted' – Either the comment or proposed amendment is considered conflicting with the objectives foreseen by the Essential Requirements applicable to cabin crew, or the comment is not shared by the Agency.
12. CRD b (resulting text) and CRD c (comments and responses) are published on the Agency's website. The Agency's Comment Response Tool is not being used due to the applied working method used as further explained above. The list of the different documents that are part of this CRD can be found in Annex I to this Explanatory Note.
13. The Agency's Opinion 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.
14. Such reactions should be received by the Agency not later than **23 August 2010** and should be submitted using the Comment-Response Tool at <http://hub.easa.europa.eu/crt/>.

⁶ Rulemaking group composition for CAT
(http://www.easa.europa.eu/ws_prod/r/doc/NPA/Review%20Group/GC%20OPS%20001%20CAT.pdf).

⁷ Rulemaking group composition for NCC
(http://www.easa.europa.eu/ws_prod/r/doc/NPA/Review%20Group/GC%20OPS%20001%20CMPA.pdf)

15. When submitting their reactions, stakeholders are kindly invited to clearly identify the issue and, if relevant, the article/paragraph in question.

Annex I to the Explanatory Note (A and B)**CRD documents**

ORIGINAL DOCUMENT	CRD #	CONTENT
N/A	CRD a	Explanatory Note
NPA 2008-17c	CRD a.1	Explanatory Note A
NPA 2009-02e	CRD a.2	Explanatory Note B
	CRD B	RESULTING TEXT
NPA 2008-17c NPA 2009-02e	CRD b.1	Cover Regulation
	CRD b.2	Part-MED
	CRD b.3	AMC/GM to Part-MED
	CRD C	COMMENTS AND RESPONSES
NPA 2008-17c	CRD c.1	Comments and Responses to Subparts A, B, C, D
	CRD c.2	Comments and Responses to AMCs
NPA 2009-02e	CRD c.3	Comments on Cabin Crew medical fitness
	CRD c.4	Comment Response Summary Table (CRST)
N/A	Information	Application and Examination forms for medical certificates LAPL

Annex II to Explanatory Note B**Explanatory memorandum
on the review of comments on NPA 2009-02e and the resulting text****A. General analysis of comments received**

1. By the closing date of the consultation period of NPA 2009-02, the 13.770 comments received were distributed as follows:
 - 610 comments on NPA 2009-02a (Explanatory Note and Appendices);
 - 7.310 comments on NPA 2009-02b (Draft Opinion and Decision Part-OPS);
 - 3.878 comments on NPA 2000-02c (Draft Opinion and Decision Part-OR - Subpart OPS);
 - 656 comments on NPA 2000-02d (Draft Opinion and Decision Part-AR - Subparts GEN, OPS and CC);
 - 941 comments on NPA 2000-02e (Draft Opinion and Decision Part-CC and Supplement to Draft Opinion Part-MED);
 - 39 comments on NPA 2000-02f (Cross-Reference Tables); and
 - 306 comments on NPA 2000-02g (Regulatory Impact Assessment (RIA)).
2. Of course, not all of these comments represented individual views. Between 30 and 40% of the comments received were identified as duplicates, meaning that the same comment had been introduced several times.
3. When assessing the comments, the primary factor considered by the Agency was the quality and pertinence of those comments, as well as the justifications provided, rather than the number of duplications.

Comments received on NPA 2009-02a – Explanatory Note

4. Among a total of 610 comments received on NPA 2009-02a, 32 of these comments related to the Explanatory memorandum on cabin crew. Chart 1 below shows their distribution.
5. 23 of these 32 comments originated from five individual operators of the same Member State and focused on the same issues that were also commented upon in NPA 2009-02e. For this reason, they will not be specifically mentioned here. They are nevertheless reported, together with the Agency's responses, in the Common Response Summary Table published in CRD c.4.

Comments received on NPA 2009-02g – Regulatory Impact Assessment (RIA)

6. Chart 2 below shows the distribution of the 306 comments that were received on the RIA. 41 of these comments related to the medical fitness of cabin crew, whilst 6 related to the issue of competence and attestation process.
7. In addition to these 47 comments specifically made to points 2.10 and 2.11 of the RIA relating respectively to cabin crew medical fitness and competence, 17 additional comments also related to cabin crew were entered on other points of the RIA.
8. This overall total of 64 comments was distributed as follows:
- 9 comments by one Member State, considering that medical fitness of cabin crew had no impact on flight safety and that aero-medical examinations and assessment would result in a significant cost increase, 50% of which would fall on the operators of that Member State;
 - 1 comment by another Member State that, conversely, considered the issue as impacting on safety, particularly in the case of single cabin crew operations;
 - 2 comments by cabin crew organisations, considering on the basis of scientific studies that the cabin crew contribution to safety was higher than reported in the RIA;
 - 52 comments by operators, associations and individual airlines, considering that the medical conditions of cabin crew had no impact on flight safety and expressing their strong disagreement against any requirement beyond EU-OPS which would lead to significant cost increase and would also raise questions of discrimination.
9. The vast majority of those 64 comments were repeated to NPA 2009-02e and are therefore not further detailed here, but reflected in the Comment Response Summary Table (CRD c.4).

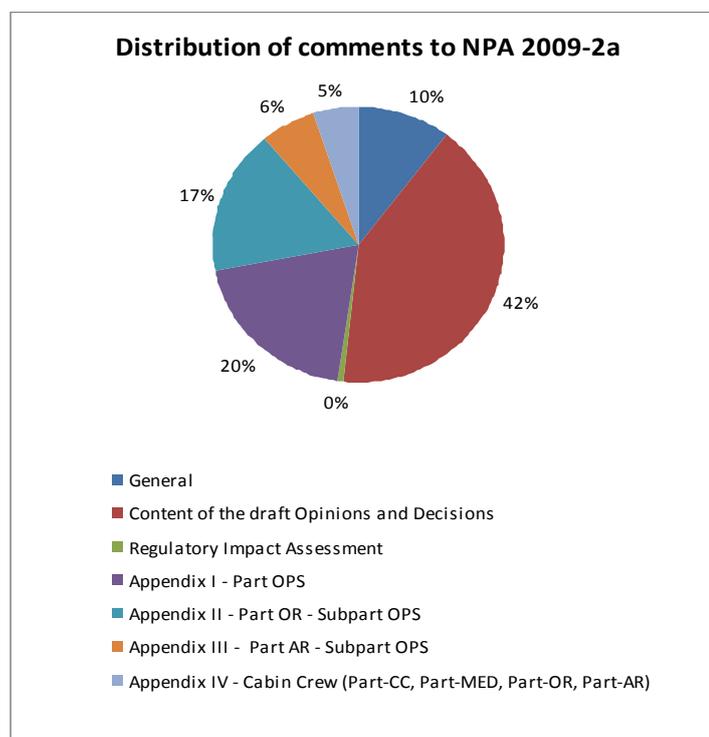
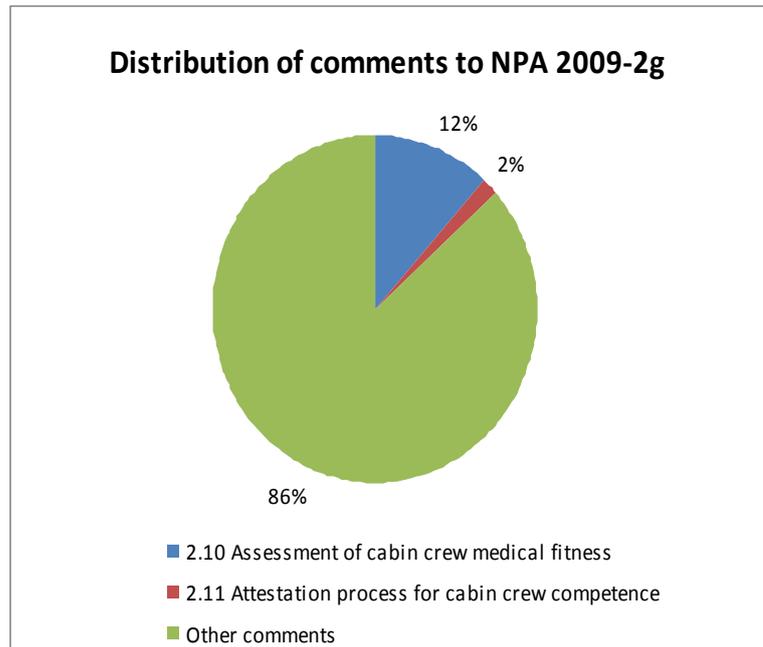
Chart 1 – Distribution of the 610 comments to NPA 2009-02a



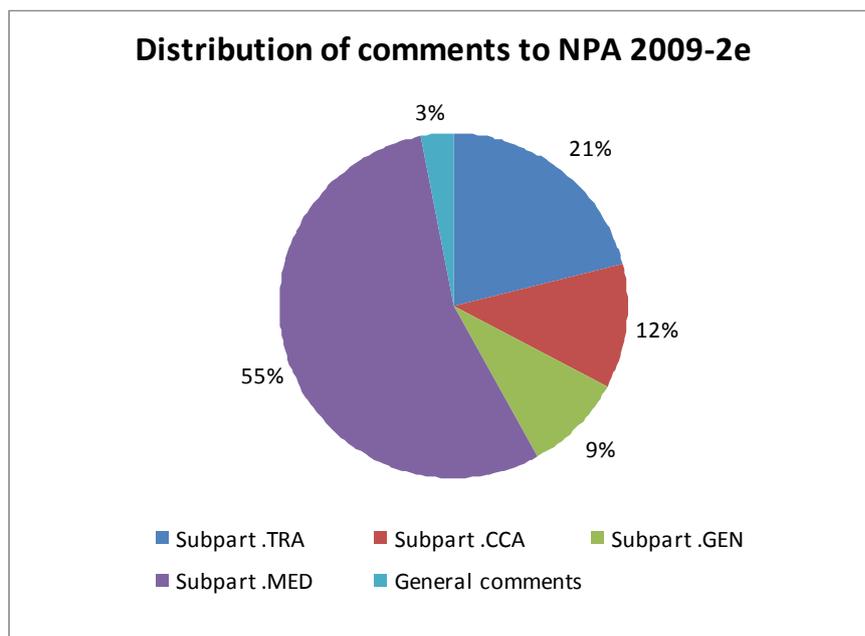
Chart 2 – Distribution of the 306 comments to NPA 2009-02g



Comments received on NPA 2009-02e

10. The following Chart 3 shows the distribution of the 941 comments received on NPA 2009-02e. 518 of these comments (55%) were made on the proposed Supplement to Part-MED for the medical fitness of cabin crew. The other comments related to Part-CC and will be reported later on when published as part of another CRD.

Chart 3 – Distribution of the 941 comments to NPA 2009-02e



B. Description of comments received and resulting text

11. The Agency reviewed carefully the comments received on NPA 2009-02e relating to the proposed Supplement to Part-MED for cabin crew medical fitness. Based on this, changes were made to the initial draft text. The following paragraphs highlight the most significant aspects and explain the reasons behind the resulting text published in CRD c.3 (clean version) and in CRD c.4 (with track changes to the initial NPA text).

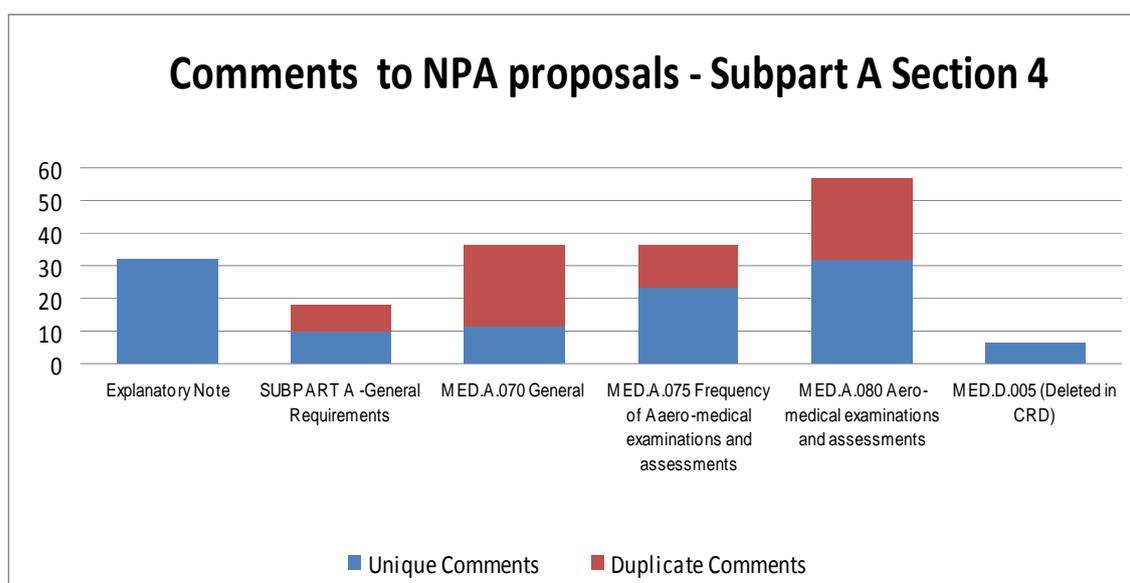
Cover Regulation

12. NPA 2009-02, as well as NPA 2008-17c, did not contain draft proposals for a Cover Regulation for the reasons that were detailed in the related Explanatory Notes (NPA 2009-02a and NPA 2008-17a). The Explanatory Notes described the intentions of the Agency regarding the possible transition measures. Based on the comments received, the Agency has prepared a draft Cover Regulation, which is published with the resulting text in CRD b.1.
13. The Cover Regulation on 'Personnel Requirements' defines the general applicability of Part-FCL and its other Annexes, as well as of Part-MED, and proposes transition measures, including as opt-outs⁸ for those going beyond 8 April 2012. The Cover Regulation first published with the CRD on Part-FCL has now been complemented with paragraphs detailing transition measures for the applicability of Part-MED, including as regards the medical fitness of cabin crew.

NPA 2009-02e - Part-MED - Requirements for medical fitness of cabin crew

14. NPA 2009-02e contained Implementing Rules that were presented under an additional Section 4 to Subpart A and an additional point to Subpart D of Part-MED, as well as a new Subpart E. Chart 4 below shows the distribution of the 148 comments made to the various segments of Subpart A. It also shows the significant proportion of duplicates (30%), particularly on MED.A.070 'General' and MED.A.080 'Aero-medical examinations and assessments'.

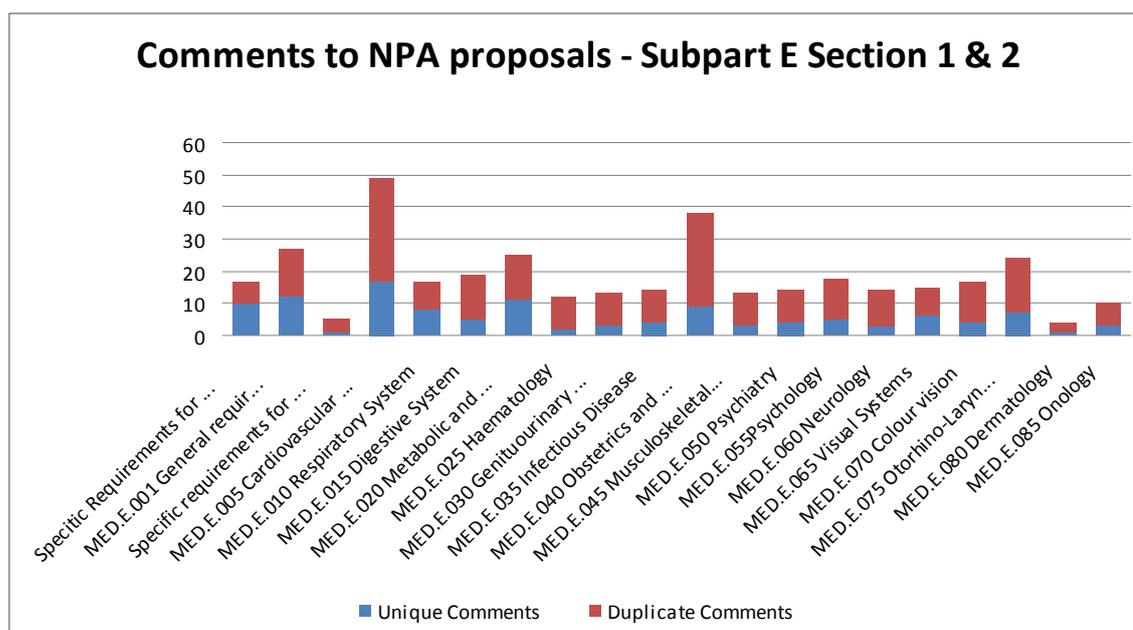
Chart 4 – Distribution of the comments to Section 4 of Subpart A (NPA)



⁸ An opt-out is a type of transition measure that leaves to the Member States the choice to postpone the implementation date of a certain provision, up to a certain time limit defined by law.

15. The proposed MED.D.005 on the General Medical Practitioner (GMP) received only six unique comments. As further explained in the Comment Response Summary Table, the proposal was not supported and has been deleted from the resulting text presented with this CRD.
16. The Subpart E proposed in the NPA received 365 comments, including 44 on MED.E.001 'General requirements' and 321 on the specific medical conditions described in the following segments from MED.E.005 'Cardiovascular system' to MED.E.085 'Oncology' Chart 5 below shows the distribution of comments between the various systems and highlights in particular the very high proportion of duplicates (up to 51% of 321).

Chart 5 – Distribution of the comments to Subpart E (NPA)



17. 47 commentators contributed. The main commentators were as follows:
- 8 Member States. Three of them disagreed with the proposals whilst one supported the NPA and the four others made proposals to amend and improve the text.
 - 4 European airlines organisations and 19 individual airlines from 9 Member States commented. Most operators disagreed with the proposals and expressed very serious concerns raised by the potentially associated cost issues. Only in a few cases, comments supported the NPA proposals.
 - 8 cabin crew organisations were generally in agreement with the NPA proposals, and requested further improvements and clarifications of the text.
 - 2 individual aero medical examiners (AME) supported the NPA and requested improvements. Conversely, a national association of AMEs shared the same views as expressed by their Member State, thus considering that the fitness of cabin crew was a matter of occupational health and only deserved simple self-assessments based on questionnaires.
- It should be noted here that 23 Member States did not comment, and that airlines from 22 Member States did not comment either.
18. When reviewing the comments in detail, the Agency applied the following method:
- The 518 comments were read and 229 duplicates were identified. Comments were assessed against the relevant Essential Requirements (ER) of the Basic Regulation. Furthermore; the pertinence and the quality of the justification provided were also

assessed as well as whether the comments were simply statements or well substantiated. Finally, special consideration was also given where the same views were expressed by several commentators, particularly when they represented different sectors or backgrounds.

- Following this assessment, it became clear that the classification (described in paragraph 11) required by the nature of the comments received had to take into particular account their compatibility with the Basic Regulation;
- The comments were summarised in Column B of the Comment Response Summary Table (CRD c.4); and
- The responses to the summarised comments were inserted in Column C of the same Comment Response Summary Table.

19. When summarising the comments, the following main issues were identified:

- Numerous comments and duplicates, mainly from operators and from those Member States that had expressed the same concerns to the RIA and the Explanatory Note, requested not to regulate beyond the EU-OPS provisions. These comments could not be accepted as conflicting with the Basic Regulation. Article 8(5)(e) requires the Agency to develop measures specifying the conditions for the cabin crew attestation. Annex IV, ER 7.b. (i) and (ii) further specified that cabin crew shall be regulated on the two main aspects identified therein, namely competence and fitness. The said conditions were therefore developed on these bases by the Agency;
- The balance between IR and AMC/GM was not considered appropriate for the medical requirements specified for assessing fitness, and it was suggested by many comments that they should be moved from IR to AMC material;
- It was also suggested that some of the specific medical requirements should be less stringent and that the same should apply to all cabin crew whether they are assigned to non-commercial or to commercial air transport operations;
- Flexibility was considered needed and it was suggested that it should be possible to assess the medical fitness of cabin crew under the relevant national occupational health system;
- It was furthermore stressed by several comments that operators should be informed on the outcome of aero-medical examinations and assessments and it was suggested that this should be done by means of some standardised paper;
- Finally, many commentators recommended that the frequency of the aero-medical examinations and assessments should be the same as for Class 2 medical certificates. These comments may originate from stakeholders of the 12 EASA Member States that already use this frequency for their cabin crew as well as base the assessments on the same medical criteria as those specified for Class 2 medical certificates.

20. When revising the NPA text on the basis of the comments summarised in paragraph 19, the following principles were followed:

- Comments compatible with the Basic Regulation were taken into account and used to improve or change the text;
- Rules were clarified where suggested;
- The balance between Implementing Rules (IR) and AMC/GM was significantly reconsidered. In particular, the medical criteria specified in IRs for the fitness assessment were transferred to AMC;
- Proportionality and flexibility were enhanced whilst addressing the diverse medical conditions and types of operations, including a possibility to conduct the aero-medical examinations and assessments under the relevant national occupational system;

- Additional GM was developed with the objective to achieve common understanding of the medical fitness required from cabin crew to perform their duties safely (task-related assessment) and to facilitate standardisation across the EU; and
 - The sub-structure of Part-MED as published in NPA 2009-02e was assessed as requiring a change aiming at placing all requirements for cabin crew in one dedicated Subpart (Subpart E in this CRD).
21. All changes envisaged as a result of the comment review were submitted to the concerned FCL.001 and OPS.001 Review Groups as already mentioned in paragraph 8. The feedback received from the written procedure reflected in most cases the comments received to the NPA and was used to further improve and clarify the resulting text that is now presented in CRD b.2 for the Implementing Rules and CRD b.3 for the AMC/GM.
 22. Further details regarding the summary of comments and the related Agency's responses can be found under each segment in the Comment Response Summary Table in CRD c.4. The Column A of this CRST also shows all changes made to the NPA text including any additions or deletions, whilst the clean version of the resulting text is published in CRD b.2 and b.3.
 23. The list below gives the new table of contents and related numbers and titles of the proposed resulting text, showing the significant transfer from the IRs to the AMC/GM that has been made as recommended by most comments. Chart 6 below shows the structure of Part-MED (Annex IV to Cover Regulation for Personnel Requirements) and where Subpart E is placed within Part-MED, whilst Chart 7 shows the horizontal structure of the Cover Regulations for the areas of Air Operations and Flight Crew Licensing.

CRD Part-MED

Subpart E

Section 1

- MED.E.001** General requirements
- MED.E.005** Aeromedical examinations and assessments
- MED.E.010** Suspension of the exercise of duties
- MED.E.015** Additional requirements for applicants for, and holders of, a cabin crew attestation in commercial air transport operations

AMC1 MED.E.015 (b) Additional requirements for applicants for, and holders of, a cabin crew attestation in commercial air transport operations

AMC1 MED.E.015 (c) Additional requirements for applicants for, and holders of, a cabin crew attestation in commercial air transport operations

Section 2

- MED.E.020** General requirements
- MED.E.025** Content of aeromedical examinations and assessments

AMC1 MED.E.025 Content of aero-medical examinations and assessments

GM1 MED.E.025 Content of aero-medical examinations and assessments

Chart 6 – Cover Regulation for Personnel Requirements

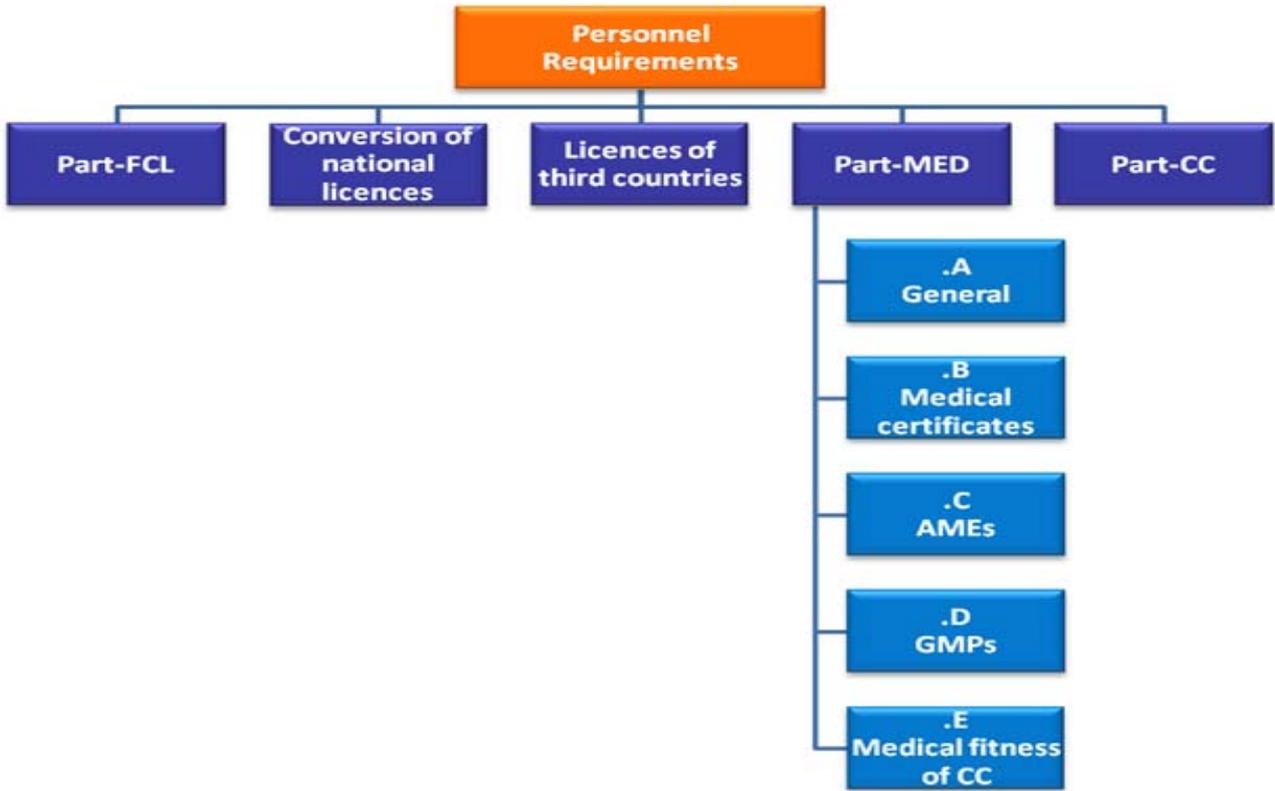


Chart 7 – BR and Cover Regulations AR – OR – OPS – PER - TCO

