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| <b>Title</b>      | Updating Part-MED and related AMC and GM |
| <b>NPA Number</b> | NPA 2017-22                              |

**UK CAA** (European.Affairs@caa.co.uk) has placed **36** unique comments on this NPA:

| Cmt# | Segment description | Page    | Comment  | Attachments |
|------|---------------------|---------|--|-------------|
| 141  | ARA.MED.125         | 9       | <p><b>Paragraph No:</b> ARA.MED.125 (c) and (d)</p> <p><b>Comment:</b> Not always appropriate for the medical assessor to issue a medical certificate. Combine (c) and (d)</p> <p><b>Justification:</b> The pilot may have been made temporarily unfit and therefore already hold a certificate with residual validity or the certificate may have expired and a renewal examination be required.</p> <p><b>Proposed Text:</b><br/> <del>(c) in case of a fit assessment, the medical assessor shall issue the medical certificate; and</del><br/> <del>(d) the medical assessor shall inform the AeMC or AME of the decision and issue a medical certificate if appropriate</del></p> |             |
| 142  | ARA.MED.125         | 9       | <p><b>Paragraph No:</b> ARA.MED.126 (b)</p> <p><b>Comment:</b> False evidence should also be included as a reason for limitation, suspension or revocation of a medical certificate</p> <p><b>Justification:</b> The UK CAA has experience of applicants attempting to obtain a medical certificate by providing false evidence/medical reports</p> <p><b>Proposed Text:</b><br/> (1) a medical certificate is falsified or obtained by a false declaration or false evidence;</p>   |             |
| 143  | ARA.MED.125         | 9       | <p><b>Paragraph No:</b> ARA.MED.126</p> <p><b>Comment:</b> Further text is required to indicate that a medical certificate shall be returned to the licensing authority following revocation.</p> <p><b>Justification:</b> Prevent misuse of medical certificates</p> <p><b>Proposed Text:</b> (e) Following revocation the medical certificate shall be returned to the licensing authority.</p>  |             |
| 144  | ARA.MED.130         | 10 - 11 | <p><b>Paragraph No:</b> ARA.MED.130 (a)(2)</p> <p><b>Comment:</b> Text "Class of medical certificate" should not be deleted</p> <p><b>Justification:</b> The removal of the text "Class of medical certificate" will require significant editorial changes throughout Part MED, Part ARA and any other Part making reference to Class 1, Class 2 or LAPL medical certificates e.g. "<b>MED.A.050 Referral</b> (a) If an applicant for a Class 1 or Class 2 medical certificate....". This may also be non-</p>   |             |

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|     |             |         | compliant with ICAO SARPS.<br><b>Proposed Text:</b> No change  |  |
| 145 | ARA.MED.130 | 10 - 11 | <b>Paragraph No:</b> ARA.MED.130 (a)(8)(i) and (ii)<br><b>Comment:</b> This change is unnecessary<br><b>Justification:</b> There is no need to change these around or to delete "other commercial operations" as the meaning will be lost i.e. the meaning of "Class 1" (on its own) will be unclear and not differentiated from "single pilot commercial operations carrying passengers"<br>Making such administrative/IT changes will be a significant administrative and cost burden to NAAs<br><b>Proposed Text:</b> No change   |  |
| 146 | ARA.MED.130 | 10 - 11 | <b>Paragraph No:</b> ARA.MED.130 (a)(8)(iv)<br><b>Comment:</b> This addition is unnecessary<br><b>Justification:</b> There is no need to add an additional Class 2 category as it will create a conflict between the periodicity of the medical certificate and the periodicity of the investigation (audiogram). It should be the duty of the AME to check the applicant's requirement for an audiogram at the time of the medical examination and ensure that the appropriate investigations occur with the correct periodicity, aligned with that of the medical certificate.<br>Making such administrative/IT changes will be a significant administrative and cost burden to NAAs<br><b>Proposed Text:</b> No change  |  |
| 147 | ARA.MED.130 | 10 - 11 | <b>Paragraph No:</b> ARA.MED.130 (a)(10), (11) and (12)<br><b>Comment:</b> These additions are unnecessary and cause confusion as to the validity dates of the certificate. These next due dates have previously been removed from the certificate as they caused considerable confusion for flight operations inspectors on the ramp and resulted in flights being grounded unnecessarily.<br><b>Justification:</b> There is no need to add additional "next due" dates they will create conflicts between the periodicity of the medical certificate and the periodicity of the investigation (ECG, audiogram and ophthalmological investigation).<br>Reference to the "ophthalmological examination" is confusing as it is not clear whether this refers to the routine examination as part of the periodic medical or where the extended ophthalmological examination for applicants with (for example) high refractive error is required.<br>In addition, making such administrative/IT changes will be a significant administrative and cost burden to NAAs<br><b>Proposed Text:</b> No change |  |
| 148 | ARA.MED.155 | 12      | <b>Paragraph No:</b> ARA.MED.155 (a)   |  |

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|     |               |      | <p><b>Comment:</b> Medical report holders should not be included in this rule.</p> <p><b>Justification:</b> Cabin crew medical reports and related medical files are not required to be held by the competent authority. If transfer of medical information is required the crew member can request a copy of their medical record in accordance with data protection legislation. To make the authority responsible for the transfer of records would be an unjustified additional administrative burden.</p> <p><b>Proposed Text:</b></p> <p>(a) Upon receiving a medical file transfer request from medical certificate or medical report holders to a new licensing authority, the existing licensing authority shall:</p>  |  |
| 139 | ARA.MED.315   | 14   | <p><b><u>ARA.MED.315 Review of examination reports</u></b></p> <p><b>Comment:</b> The medical assessor needs oversight of the review of all reports but this task may be delegated or electronically validated in specified circumstances.</p> <p><b>Justification:</b> Many processes can be automated and numerical values checked by an automated process and suitably trained staff can check and verify data with oversight by the medical assessor.</p> <p><b>Proposed Text:</b> The licensing authority shall require the medical assessor to have a process in place for the medical assessor to</p>  |  |
| 140 | ARA.MED.325   | 14   | <p><b><u>ARA.MED.325 Secondary review procedure</u></b></p> <p><b>Comment:</b> The proposed text does not necessarily require medical involvement which is essential for decision making.</p> <p><b>Justification:</b> This should be a medical review with medical and operational experts as necessary.</p> <p><b>Proposed Text:</b> The competent licensing authority shall establish a procedure for the review of borderline and contentious cases and cases where an applicant requests a review, with independent medical advisors, experienced in the practice of aviation medicine, to consider and advise on an applicant's fitness for medical certification in accordance with the applicable medical requirements and accredited medical conclusion.</p>   |  |
| 149 | ARA.MED.330   | 15   | <p><b>Paragraph No:</b> ARA.MED.330 (b)</p> <p><b>Comment:</b> It is more important to have an appropriate protocol than a set number of participating licensing authorities.</p> <p><b>Justification:</b> Having a specified minimum number of licensing authorities does not fulfil the safety aim of the regulation. There is no justification to increase the number of participating licensing authorities required.</p> <p><b>Proposed Text:</b> In order to undertake research, a competent licensing authority, in cooperation with at least one two other competent licensing authorities, may develop and evaluate a medical assessment certification protocol, based on which these competent licensing authorities may issue a defined number of pilot medical certificates with appropriate limitations.</p> |  |
| 150 | Appendix V to | 16 - | <p><b>Paragraph No:</b> <b><u>APPENDIX V TO ANNEX VI PART-ARA -</u></b></p>   |  |

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|     | Part-ARA – Certificate for AeMCs                | 17      | <p><u>CERTIFICATE FOR AERO-MEDICAL CENTRES (AeMCs)</u></p> <p><b>Comment:</b> All certificates and attachments should be AMC material.</p> <p><b>Justification:</b> Formats may need to vary according applicable national law and available IT systems, taking account of future developments where certificate information may be available electronically negating the need to hold a physical certificate.</p> <p><b>Proposed Text:</b> No change but move to AMC</p>   |  |
| 152 | Appendix V to Part-ARA – Certificate for AeMCs  | 16 - 17 | <p><b>Page No:</b> 17</p> <p><b>Paragraph No:</b> <u>APPENDIX V TO ANNEX VI PART-ARA - CERTIFICATE FOR AERO-MEDICAL CENTRES (AeMCs)</u></p> <p><b>Comment:</b> The information in attachments should be part of the certificate</p> <p><b>Justification:</b> No need to have separate documents</p> <p><b>Proposed Text:</b> Merge certificate and attachment</p>   |  |
| 151 | Appendix VII to Part-ARA – Certificate for AMEs | 18 - 19 | <p><b>Paragraph No:</b> <u>APPENDIX VII TO ANNEX VI PART-ARA</u></p> <p><b>Comment:</b> All certificates and attachments should be AMC material.</p> <p><b>Justification:</b> Formats may need to vary according applicable national law and available IT systems, taking account of future developments where certificate information may be available electronically negating the need to hold a physical certificate.</p> <p><b>Proposed Text:</b> No change but move to AMC</p>   |  |
| 153 | Appendix VII to Part-ARA – Certificate for AMEs | 18 - 19 | <p><b>Paragraph No:</b> <u>APPENDIX VII TO ANNEX VI PART-ARA</u></p> <p><b>Comment:</b> The information in attachments should be part of the certificate</p> <p><b>Justification:</b> No need to have separate documents</p> <p><b>Proposed Text:</b> Merge certificate and attachment</p>  |  |
| 154 | ORA.AeMC.160                                    | 20      | <p><b>Paragraph No:</b> <u>ORA.AeMC.160 Reporting</u></p> <p><b>Comment:</b> Not clear what is meant by “risk factors” – does this mean data from the analysis of the AeMCs (safety) management activities?</p> <p><b>Justification:</b> Clarify meaning of text</p> <p><b>Proposed Text:</b> <u>The AeMC shall provide the competent authority with statistical reports regarding the aero-medical assessments of applicants, including reports of the drugs and alcohol screening and risk factors identified safety management activities.</u></p> |  |
| 155 | ORA.AeMC.200                                    | 21      | <p><b>Paragraph No:</b> <u>ORA.AeMC.200 Management system (b)</u></p> <p><b>Comment:</b> Not clear why this text has been added or why it is needed.</p>  |  |
| 156 | ORA.AeMC.205                                    | 21      | <p><b>Paragraph No:</b> <u>ORA.AeMC.205 Contracted activities</u></p>   |  |

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|     |                                     |         | <p>Comment: Current text is not clear concerning what tests must be performed within the organisation and what can be contracted out and how.</p> <p>Justification: Edited for clarity</p> <p>Proposed Text:<br/>Notwithstanding ORA.GEN.205:</p> <p>(a) <del>Minimum</del> The mandatory required aero-medical test and examinations for the issue of a class 1 or 3 medical certificate shall be performed within the organisation of the AeMC, in accordance with the scope and privileges defined in the terms of approval attached to the AeMC's certificate.</p> <p>(b) If the mandatory requirements performed are not performed within the organisation and are contracted out, the organisation shall ensure the contracted service or product conforms to the applicable requirements.</p> <p>(c) Additional medical examinations and investigations may be performed by other <del>contracted</del> individual experts or organisations. The organisation shall ensure that when contracting any part of its activity, the contracted service or product conforms to the applicable requirements.</p> |  |
| 157 | ORA.AeMC.210                        | 21      | <p><b>Paragraph No:</b> ORA.AeMC.210 Personnel requirements (a)(3)</p> <p><b>Comment:</b> Not clear why this text has been added or why it is needed</p>   |  |
| 158 | AMC/GM to Part-ARA – AMC1 ARA.MED.1 | 22      | <p><b>Paragraph No:</b> AMC1 ARA.MED.120 (a)</p> <p><b>Comment:</b> The text should not be changed.</p> <p><b>Justification:</b> Rule should be competency and not time based. The AMC should not adversely impact doctors training in the medical specialty of Aviation Medicine in countries where this is recognised. This may adversely impact doctors in countries with a low availability of suitably qualified doctors.</p> <p><b>Proposed Text:</b> No change to original:<br/>"have considerable experience of aero-medical practice <del>held class 1 privileges for at least 5 years</del> and have undertaken a minimum of 200 class 1 medical examinations, or equivalent;"</p>   |  |
| 159 | GM1 ARA.MED.120                     | 23 - 25 | <p><b>Page No:</b> 24-25</p> <p><b>Paragraph No:</b> GM1 ARA.MED.120 (c)</p> <p><b>Comment:</b> Text appears unsuitable for guidance material</p> <p><b>Justification:</b> This appears to be explanatory text rather than guidance material.</p> <p><b>Proposed Text:</b> <del>Whether the sharing of medical assessors is concluded directly between two NAAs or through a sharing platform, sustainability can only be ensured if all stakeholders are willing to consider global optimisation as a priority. The challenge is that the management system of each NAA may systematically reduce its resources so that all qualified medical assessors are fully occupied all the times. Such planning strategy does not provide any extra margin for contingencies and may easily drift towards understaffing. It is</del></p>  |  |

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|     |                     |            | <p>always difficult to swiftly adjust the number of permanently employed experts to the short term oversight needs. Therefore, while attempting to 'optimise' its own resources, each NAA may rely more and more on the experts from other NAAs and further reduce its staff. While this may work for a limited period of time, in the long run the sharing of experts may simply become impossible as all NAAs will be requesting qualified medical assessors while no NAA would be able to provide any. A similar reasoning applies when experts from the industry are shared.</p> <p>-</p> <p>The concept of sharing implies availability of resources. Availability means extra capacity. Therefore all stakeholders involved in the sharing are expected to coordinate their staffing strategies globally. This ensures global optimisation by reallocating resources so that no expert is underused and that the costs are shared based on the level of support obtained. Additionally, it is expected that activity planning is coordinated among all involved stakeholders.</p> |  |
| 160 | AMC1<br>ARA.MED.128 | 25         | <p><b>Paragraph No:</b> AMC 1 ARA.MED.128 Consultation Procedure</p> <p><b>Comment:</b> The definition of "minutes" implies a formal meeting which is not what is intended. Change from "minutes" to "a record".</p> <p><b>Justification:</b> Clarity</p> <p><b>Proposed Text:</b> This procedure should include at least <del>a record</del> <b>a record</b> the <del>minutes</del> of the consultation.</p>   |  |
| 161 | AMC1<br>ARA.MED.130 | 25 -<br>28 | <p><b>Paragraph No:</b> AMC1 ARA.MED.130 IX Expiry dates</p> <p><b>Comment:</b> Additional expiry date for Class 2 IR not required as will always be the same as for Class 2 expiry date.</p> <p><b>Justification:</b> It is not clear why this has been added. This will create significant software issues and economic burden for NAAs without adding any additional safety or other benefit.</p> <p><b>Proposed Text:</b> Delete "Class 2 with IR (dd/mm/yyyy or 'N/A')"</p>  |  |
| 162 | AMC1<br>ARA.MED.130 | 25 -<br>28 | <p><b>Paragraph No:</b> AMC1 ARA.MED.130 Medical Certificate Format IX Expiry dates</p> <p><b>Comment:</b> Addition of ophthalmological examination is not required.</p> <p><b>Justification:</b> The requirement for a comprehensive eye examination varies with degree of refractive error and class of medical certificate. AMEs are required to ensure that an appropriate ophthalmological review has taken place before issuing a medical certificate. Exceeding the next due date may result in a ramp inspector grounding the pilot unnecessarily.</p> <p><b>Proposed Text:</b> Delete "Ophthalmological examination"</p>   |  |
| 163 | AMC1<br>ARA.MED.130 | 25 -<br>28 | <p><b>Paragraph No:</b> AMC1 ARA.MED.130 Medical Certificate Format IX Expiry dates</p> <p><b>Comment:</b> The addition of next due dates for audiograms and ECGs has previously caused significant service disruption for airlines</p> <p><b>Justification:</b> These dates were originally included on the medical certificate (JAA). They were removed as they caused confusion amongst ramp inspectors who wrongly interpreted these dates as</p>   |  |

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|     |                              |            | <p>representing certificate expiry dates. Flights have been grounded because ramp inspectors outside Europe have not allowed them to continue with pilots who had a next due date for an ECG or audiogram stated on their medical certificate that had been exceeded. The ramp inspectors have taken the 'next due' dates as absolutes and did not recognise that there was a difference between the next due dates and the certificate expiry dates.</p> <p><b>Proposed Text:</b> Delete all "next" due dates for Class 1, 2 and LAPL.</p>   |  |
| 164 | AMC1<br>ARA.MED.130          | 25 -<br>28 | <p><b>Paragraph No:</b> AMC1 ARA.MED.130 Medical Certificate Format</p> <p><b>Comment:</b> Inflight incapacitation should require the medical certificate holder to seek advice from an AeMC, AME or GMP.</p> <p><b>Justification:</b> To assure continued fitness of the certificate holder.</p> <p><b>Proposed Text:</b><br/>(b) In addition, licence holders shall, without undue delay and before exercising the privileges of their licence, seek aero-medical advice from the AeMC, AME or GMP, as applicable, when they:<br/>(1) have undergone a surgical operation or invasive procedure;<br/>(2) have commenced the regular use of any medication;<br/>(3) have suffered any significant personal injury involving incapacity to function as a member of the flight crew;<br/>(4) have been suffering from any significant illness involving incapacity to function as a member of the flight crew;<br/>(5) are pregnant;<br/>(6) have been admitted to hospital or medical clinic; or<br/>(7) first require correcting lenses.<br/>(8) have suffered any inflight impairment or incapacitation</p>   |  |
| 165 | GM1<br>ARA.MED.135(b)<br>(c) | 37 -<br>40 | <p><b>Paragraph No:</b> GM1 ARA.MED.135 (b) Ophthalmology Examination Report Form and GM1 ARA.MED.135 (c) Otorhinolaryngology (ENT) Examination Report Form</p> <p><b>Comment:</b> Items 301 and 401 respectively</p> <p><b>Justification:</b> Consent does not match the changes made to the application form on page 30</p> <p><b>Proposed Text:</b></p> <p><del>CONSENT TO RELEASE OF MEDICAL INFORMATION:</del> I hereby authorise the release of declare that I have been informed and I understand that all information provided to my AME contained in this report, and any or all its attachments to the AME and, where necessary and all information which are provided to my licensing authority and that relates to me , may be released to the medical assessor of the my licensing authority, other health professionals and medical administration staff as part of the aero-medical assessment process and to the medical assessor of the competent authority of my AME, recognising that these documents or electronically stored data are to be used for completion of a aero-medical assessment and for oversight purpose will become and remain the property of the licensing authority, providing that I or my physician may have access to them according to national law. Medical confidentiality will be respected at all times.</p> |  |
| 166 | GM1<br>ARA.MED.155           | 43         | <p><b>Paragraph No:</b> GM1 ARA.MED.155 Transfer of medical files</p> <p><b>Comment:</b> Title is incorrect</p>   |  |

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|     |                      |    | <p><b>Justification:</b> Clarity.</p> <p><b>Proposed Text:</b><br/> <del>APPLICATION FORM TO INFORMATION FORM FOR THE TRANSFER AEROMEDICAL RECORDS FOR THE PURPOSE OF A CHANGE OF STATE OF LICENCE ISSUE OF A PILOT LICENCE MEDICAL DETAILS, IN CONFIDENCE</del></p>  |  |
| 167 | GM1<br>ARA.MED.155   | 43 | <p><b>Paragraph No:</b> GM1 ARA.MED.155 Transfer of medical files</p> <p><b>Comment:</b> The form does not state the intended recipient of the aeromedical records.</p> <p><b>Justification:</b> Clarity.</p> <p><b>Proposed Text:</b><br/>         Divide Item 1 into 1(a) Current state of licence issue and 1(b) Proposed state of licence issue</p>   |  |
| 168 | AMC1<br>ARA.MED.200  | 44 | <p><b>Paragraph No:</b> AMC1 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate</p> <p><b>Comment:</b> No need to differentiate between those AMEs with or without extended privileges</p> <p><b>Justification:</b> Following the issue of an AME certificate there is an ongoing process of oversight, including inspections. This should not be affected by an AME extending their privileges.</p> <p><b>Proposed Text:</b><br/>         INSPECTION OF THE AME PRACTICE<br/>         Before issuing the AME certificate, the competent authority should conduct an inspection of the AME practice to verify compliance with ARA.MED.200(a).</p> <p><del>For applicants for an AME Certificate to exercise the privileges of class 2 medical certification only, a virtual inspection of the AME premises may be acceptable. In case of concerns regarding compliance with this regulation, an on-site inspection should be conducted.</del></p> |  |
| 169 | GM1<br>ARA.MED.330   | 46 | <p><b>Paragraph No:</b> GM1 ARA.MED.330 Special medical circumstances (b)</p> <p><b>Comment:</b> Remove reference to a specific document.</p> <p><b>Justification:</b> The text refers to a document which is outside EASA and the EC control.</p> <p><b>Proposed Text:</b><br/>         The protocol and its implementation should comply with <b>medical, ethical</b> the principles described in the following publication by the World Medical Association (WMA): 'WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects', as last amended.</p>  |  |
| 170 | AMC1<br>ORA.AeMC.115 | 46 | <p><b>Paragraph No:</b> AMC1 ORA.AeMC.115 Application (b)</p> <p><b>Comment:</b> We do not understand what is meant by this sentence.</p> <p><b>Justification:</b> Needs to be clarified</p>  |  |

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| 171 | AMC1<br>ORA.AeMC.205 | 47 | <p><b>Paragraph No: AMC1 ORA.AeMC.205 Contracted activities (1)</b></p> <p><b>Comment:</b> The paragraph concerns contracted activities but this is not reflected in the text and correction to spelling of specialties.</p> <p><b>Justification:</b> Clarity</p> <p><b>Proposed Text:</b> The minimum required medical <del>examinations</del> <b>contracted activities</b> should at least encompass the following specialties: ophthalmology including colour vision, otorhinolaryngology, cardiology and mental health</p>  |  |
| 172 | AMC1<br>ORA.AeMC.205 | 47 | <p><b>Paragraph No: AMC1 ORA.AeMC.205 Contracted activities (1)</b></p> <p><b>Comment:</b> Remove reference to an otorhinolaryngology specialist.</p> <p><b>Justification:</b> Reports are very rarely required from an otorhinolaryngology specialist.</p> <p><b>Proposed Text:</b> The minimum required medical <del>examinations</del> <b>contracted activities</b> should at least encompass the following specialties: ophthalmology including colour vision, <del>otorhinolaryngology</del>, cardiology and mental health</p>   |  |
| 173 | AMC1<br>ORA.AeMC.210 | 47 | <p><b>Paragraph No: AMC1 ORA.AeMC.210 Personnel requirements (a)</b></p> <p><b>Comment:</b> The requirements should be competency and not time based.</p> <p><b>Justification:</b> The Head of the AeMC should have significant experience in Aviation Medicine and ideally a higher qualification than just the basic and advanced courses.</p> <p><b>Proposed Text:</b> The aero-medical examiner (AME) should have held <del>AME class 1</del> <b>privileges, as applicable in accordance with the scope defined in the terms of approval attached to the AeMC's certificate for at least 5 years</b> and have performed at least 200 aero-medical examinations for a class 1 <b>and/or class 3</b> medical certificate before being nominated as head of an AeMC. <b>A higher qualification in Aviation Medicine is preferable.</b></p> |  |
| 174 | AMC1<br>ORA.AeMC.215 | 48 | <p><b>Paragraph No: AMC1 ORA.AeMC.215 Facility requirements</b></p> <p><b>Comment:</b> Exercise ECGs should be available at the AeMC or arranged with a service provider.</p> <p><b>Justification:</b> Exercise ECGs require the immediate availability of an emergency care team which should not be a requirement for AeMCs.</p> <p><b>Proposed Text:</b></p> <p>MEDICAL-TECHNICAL FACILITIES<br/>The medical-technical facilities of an AeMC should consist of the equipment of a general medical practice and, in addition, of <b>equipment for:</b></p> <p>(a) Cardiology<br/>Facilities to perform:<br/>(1) 12-lead resting ECG;<br/><del>(2) stress exercise ECG;</del></p>  |  |

- (3) 24-hour blood pressure monitoring; and
- (4) 24-hour heart rhythm monitoring.....

.....(f) The following facilities should be available at the AeMC or arranged with a service provider:

- (1) clinical laboratory facilities; and
- (2) ultrasound of the abdomen.
- (3) exercise ECG