



Legal and Ethical Practice Confidentiality and Privacy Regulations



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Aeromedical Examiners and Medical Assessors shall adhere to legal requirements and ethical principles in aeromedical practice, to ensure the integrity, safety, and professionalism of aeromedical evaluations.

Effective communication, transparency, and collaboration with Clients, Colleagues, and regulatory authorities are essential for maintaining ethical standards and legal compliance in aeromedical practice.



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LEGAL ASPECTS

- Regulatory compliance – Adhere to the **REGULATIONS** set forth by CAA
- Professional Standards – Adhere to the **STANDARDS** set forth by CAA & State Medical Council.



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LEGAL CONSIDERATIONS

Regulatory Compliance

Adherence to aviation regulatory standards set by ICAO, State Authorities(CAAV)
Compliance with specific regulations governing pilot medical certification,
E.g. FAR Part 67 in the United States or Part-MED in Europe or State Authority regulations.

Professional Licensure

Maintain appropriate Medical licensure and Certification required to practice aeromedical medicine and conduct aeromedical examinations.

LEGAL CONSIDERATIONS

1.2.4.7 Applicants for licences or ratings for which medical fitness is prescribed shall sign and furnish to the medical examiner a declaration stating whether they have previously undergone such an examination and, if so, the date, place and result of the last examination. They shall indicate to the examiner whether a Medical Assessment has previously been refused, revoked or suspended and, if so, the reason for such refusal, revocation or suspension.

1.2.4.7.1 Any false declaration to a medical examiner made by an applicant for a licence or rating shall be reported to the Licensing Authority of the issuing State for such action as may be considered appropriate.

Obtain informed consent from individuals undergoing aeromedical examinations, ensuring they understand the purpose, risks, and potential outcomes of the assessment process.

LEGAL CONSIDERATIONS

1.2.4.11 Medical confidentiality shall be respected at all times.

1.2.4.11.1 All medical reports and records shall be securely held with accessibility restricted to authorized personnel.

1.2.4.11.2 When justified by operational considerations, the medical assessor shall determine to what extent pertinent medical information is presented to relevant officials of the Licensing Authority.

Data Protection Laws

Medical information obtained during aeromedical assessments is **subject to data protection Standards. AMEs & MAs must ensure that the collection, storage, and transmission of medical data comply with these regulations to protect the confidentiality and privacy of individuals undergoing assessment.**

LEGAL CONSIDERATIONS

Training and Education

1.2.4.6 Contracting States shall designate medical examiners, qualified and licensed in the practice of medicine, to conduct medical examinations of fitness of applicants for the issue or renewal of the licences or ratings specified in Chapters 2 and 3, and of the appropriate licences specified in Chapter 4.

1.2.4.6.1 Medical examiners shall have received training in aviation medicine and shall receive refresher training at regular intervals. Before designation, medical examiners shall demonstrate adequate competency in aviation medicine.

1.2.4.6.2 Medical examiners shall have practical knowledge and experience of the conditions in which the holders of licences and ratings carry out their duties.

Note.— Examples of practical knowledge and experience are flight experience, simulator experience, on-site observation or any other hands-on experience deemed by the Licensing Authority to meet this requirement.

1.2.4.6.3 **Recommendation.**— *The competence of a medical examiner should be evaluated periodically by the medical assessor.*



ETHICAL CONSIDERATIONS

Beneficence and Non-Maleficence

Prioritize the well-being of individuals undergoing aeromedical evaluations and certification, striving to maximize benefits while minimizing harm.

Professional Integrity

Upholding honesty, integrity, and professionalism in all aspects of aeromedical practice. Maintaining objectivity and avoiding conflicts of interest that could undermine the integrity of assessments.

Client Autonomy

Respecting the autonomy of individuals undergoing aeromedical assessments and involving them in decision-making processes.

Considering the preferences, values, and wishes of individuals in certification decisions.



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ETHICAL CONSIDERATIONS

Respect for Dignity

Treating individuals with dignity, respect, and empathy during aeromedical assessments.

Ensuring assessments are conducted in a manner that preserves the dignity and autonomy of individuals.

Justice and Equity

Ensuring fairness, equity, and impartiality in aeromedical assessments and certification decisions.

Avoiding discrimination or bias based on factors such as race, ethnicity, gender, or socioeconomic status.

ETHICAL CONSIDERATIONS

Client Advocacy

Advocating for the health, safety, and welfare of individuals undergoing aeromedical assessments.

Ensuring assessment processes are conducted in a manner that protects the rights and interests of individuals seeking certification.

1.2.4.3 The Licensing Authority shall implement appropriate aviation-related health promotion for licence holders subject to a Medical Assessment to reduce future medical risks to flight safety.

Note 1.— Standard 1.2.4.2 indicates how appropriate topics for health promotion activities may be determined.

Note 2.— Guidance on the subject of health promotion activities is contained in the Manual of Civil Aviation Medicine (Doc 8984).



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Universal Safety Oversight Audit Programme Continuous Monitoring Approach (USOAP CMA)

AEROMEDICAL EVIDENCE & DOCUMENTATION

Aeromedical Services, Civil Aviation Authority of Sri Lanka.



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Preparing for an ICAO-USOAP Continuous Monitoring Approach (CMA) audit and documentation process involves implementing robust quality assurance (QA) measures and maintaining thorough documentation to demonstrate compliance with international aviation safety standards.



STEP BY STEP - HOW TO PREPARE

Understand ICAO Standards

Familiarize yourself with the International Civil Aviation Organization (ICAO) standards and recommended practices (SARPs) relevant to your area of operation, including those related to aeromedical standards, aviation medicine, and medical certification.

Establish a Quality Management System (QMS)

Develop and implement a comprehensive Quality Management System (QMS) tailored to your aeromedical practice, incorporating policies, procedures, and processes to ensure compliance with regulatory requirements and best practices.

Define roles, responsibilities, and authorities for personnel involved in aeromedical assessments and certification processes.



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STEP BY STEP - HOW TO PREPARE

Conduct Internal Audits

Regularly conduct internal audits of your aeromedical practice to assess compliance with ICAO standards, regulatory requirements, and organizational policies.

Review documentation, procedures, and practices related to aeromedical assessments, medical records management, confidentiality, informed consent, and Client rights.

Document Management

Establish documentation processes to record all aspects of aeromedical assessments, including medical histories, physical examinations, test results, certification decisions, and follow-up actions.

Maintain accurate, complete, and up-to-date medical records in accordance with legal, regulatory, and ethical standards.



STEP BY STEP - HOW TO PREPARE

Develop Audit Checklists

Develop audit checklists based on ICAO SARPs, regulatory requirements, and industry best practices for aeromedical assessments and medical certification.

Ensure audit checklists cover all relevant areas, including personnel qualifications, equipment maintenance, documentation standards, confidentiality protocols, and patient rights.

Conduct Training and Awareness Programs

Provide training and awareness programs for personnel involved in aeromedical assessments to ensure understanding of ICAO standards, regulatory requirements, and organizational policies.



STEP BY STEP - HOW TO PREPARE

Implement Corrective Actions

Take prompt corrective actions to address any deficiencies or non-conformities identified during internal audits or quality assurance reviews.

Document corrective actions taken, including root cause analysis, corrective measures implemented, and follow-up actions to prevent recurrence.

Conduct pre-audit internally

Prepare for external audits, through internal audits by reviewing audit requirements, standards, and procedures.

Ensure all documentation and records are organized, accessible, and up-to-date for review by ICAO auditors.



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STEP BY STEP - HOW TO PREPARE

Document Compliance

Maintain comprehensive documentation of your quality assurance activities, internal audits, corrective actions, and compliance with ICAO standards and regulatory requirements.

Ensure documentation is readily available for review by auditors during external audits, demonstrating your organization's commitment to quality and safety in aeromedical practice.

By following these steps and implementing a proactive approach to quality assurance and audit processes, you can prepare effectively for ICAO-USOAP CMA audits and demonstrate compliance with international aviation safety standards in your aeromedical practice.

AEROMEDICAL RELATED ICAO PQs

All together Aeromedical **17** specific PQs

PQ number	PQ number	PQ number	PQ number
3.401	3.411	3.421	3.457
3.403	3.415	3.422	3.453
3.405	3.417	3,423	3.459
3.409	3.419	3.451	3.461
	3.463		

CAA need to show the evidences of implementation
Documentation evidences – Regulations & Guidance Material

AEROMEDICAL RELATED ICAO PQs

3.401 – PEL – CE – 2

Has the State promulgated regulations for medical examinations of applicants of various licences by medical examiners?

1. Verify regulations regarding medical provisions for licensing, including designation of medical examiners and requirement of a medical assessor.
2. Review regulations for the applicant to sign and furnish to medical examiners, a declaration, whose content conforms to the requirements of Annex 1.
3. Check promulgation of latest amendments to Annex 1.

AEROMEDICAL RELATED ICAO PQs

3.403 – PEL – CE – 3

Does the State use the services of medical assessors to evaluate reports submitted to the Licensing Authority by designated medical examiners (DME)?

- 1) Qualifications, experience, functions and responsibility of the medical assessor must be clearly described.
- 2) Alternative systems can be acceptable, but they must guarantee effective oversight of all DMEs or medical centres/facilities.
- 3) Review evidence to ensure effective implementation, e.g. list of DMEs and medical assessors, audit reports of DMEs and analysis of outcomes of medical assessments

AEROMEDICAL RELATED ICAO PQs

3.417 – PEL – CE – 7

Has the Licensing Authority implemented a system to ensure the confidentiality of medical reports and records at all times?

- 1) Ensure the Licensing Authority checks the confidentiality system at designated medical examiners' (DME) facilities or/and medical centres.**
- 2) Check confidentiality system of the reports kept by Licensing Authority.**
- 3) Check the policy and procedures established to determine to what extent pertinent medical information is presented to relevant officials of the Licensing Authority (special limitations due to medical issues) and other stakeholders.**
- 4) Review reports/complaints for any breach of medical confidentiality.**

AEROMEDICAL RELATED ICAO PQs

3.463

Has the State implemented appropriate aviation-related health promotion for licence holders subject to a medical assessment?

- 1) Verify analysis of in-flight incapacitation events and findings during medical assessments.**
- 2) Review list of appropriate topics identified for health promotion.**
- 3) Review evidence to confirm effective implementation, e.g. communication with stakeholders.**



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Aeromedical Services, Civil Aviation Authority of Sri Lanka.