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A UN SPECIALIZED AGENCY

PEL PQs in USOAP CMA





Outline

- **ICAO USOAP CMA overview**
- **Updates on USOAP CMA PEL PQs**
- **Review of PEL PQs**
- **SMS in MED**
- **Common examples**
- **Discussion**



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USOAP CMA

Universal Safety oversight Audit Program (USOAP) Continuing Monitoring Approach (CMA)

Activity in which ICAO **assesses the effective implementation** of the eight critical elements (CEs) of safety oversight and accident and serious incident investigation systems by conducting a **systematic and objective review** of a State's safety oversight and accident and incident investigation system.



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USOAP CMA PQ 2024

- **Applicable date 1 July 2025**
- **Total PQ 851 (1200+ SARPS/GM/flexibility)**
- **PEL PQ 100**
- **MED PQ 17**
- **Revised MED PQ 4**
- **4 PQs revised for guidance to auditor**
- **2 PQs revised for clarity**



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Protocol Question (PQ)

The **primary tool** used in USOAP to assess the level of **effective implementation** of a State's safety oversight system based on the CEs. (for audits and validations) and the level of maturity of implementation and maintenance of a State's Safety Programme (for SSPIAs)



Priority Protocol Question (PPQ)

A subset of Protocol Questions (PQ) that, if found not satisfactory, may indicate a lack of capability by a State to **identify and/or resolve** operational safety and fundamental accident investigation deficiencies effectively, and consequently, its inability to conduct safety oversight or a proper accident investigation.

Findings related to PPQs can potentially result in an elevated risk of Significant Safety Concerns.



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Specific Guidelines for PEL

- For the conduct of medical assessments, the auditor should take note of whether the State has **designated medical examiners or has delegated the assessment tasks to another organization.**



Protocol Question example

PQ #	Protocol Question	Guidance for review Evidence	ICAO References	P P Q	CE #
3.415	Does the Licensing Authority perform medical assessment audits?	<p>1) The purpose of such audits is to ensure that designated medical examiners meet applicable standards for good medical practice and aeromedical risk assessment. Guidance on aeromedical risk assessment is found in the Manual of Civil Aviation Medicine (Doc 8984).</p> <p>2) Confirm that audit process is established.</p> <p>3) Review evidence to confirm effective implementation, i.e. audit reports.</p>	STD A1 1.2.4.9.1 GM Doc 8984	Y e s	CE-7



PQ 3.401-CE2

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.



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PQ 3.403 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) Review the **process and documented evidence** of the appointment of the medical assessor.
- 3) Alternative systems can be acceptable, but they must guarantee evaluation of medical reports and effective oversight of all DMEs, medical centres/facilities.



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PQ 3.405 CE-6 PPQ

Has the State implemented a process for the **evaluation of medical reports** submitted by the designated medical examiners (DME)?

1) Verify that the process and methods in place for the evaluation of medical reports comply with Docs 8984 and 9379.

2) Review evidence to confirm effective implementation, e.g. **audit reports of medical assessments** and analysis of medical outcomes.



PQ 3.409 CE-8

Has the State established the appropriate actions to be taken in case of a **false declaration by an applicant** to a designated medical examiner (DME)?

- 1) Review procedures outlining actions to be taken.
- 2) Review evidence to confirm effective implementation, i.e. reports and evidence of a graduated response system (warnings, sanctions, etc. that have been issued).



PQ3.411 CE-6

Do designated medical examiners (DME) **systematically submit signed reports** to the Licensing Authority after completing the medical examination of an applicant?

1) If the medical examination is carried out by 2 or more examiners, verify that an **appointed examiner is responsible** for coordinating the results and signing of the report.

2) If reports are submitted electronically, **verify that adequate identification** of the examiner has been established.



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- 3) Review evidence to confirm effective implementation, i.e. records of **submission and acknowledgement of receipt**.
- 4) Verify that all reports are available at the Licensing Authority for proper review and analysis by an appropriately qualified and experienced medical personnel (even if the State does not employ a medical assessor).
- 5) Verify that detailed medical information is available only through the medical section or medical assessor to ensure **medical confidentiality**.



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PQ 3.415 CE-7 PPQ

Does the Licensing Authority perform **medical assessment audits**?

- 1) Confirm that audit process is established.
- 2) Review evidence to confirm effective implementation, i.e. audit reports.



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Note to the auditor:

1) The purpose of such audits is to ensure that designated medical examiners **meet applicable standards for good medical practice and aeromedical risk assessment.**

2) Guidance on aeromedical risk assessment is found in the Manual of Civil Aviation Medicine (Doc 8984).



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PQ 3.417 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.



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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.



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PQ 3.419 CE-6 PPQ

If the medical Standards prescribed in Chapter 6 of Annex 1 for a particular licence type are not fully met, has the State implemented a system for the **possible issuance or renewal** of the appropriate medical assessment following conditions as stipulated in Annex 1?

1) Confirm that the appropriate medical assessment is not issued or renewed unless the following conditions are fulfilled:

a) accredited medical conclusion indicates that, in special circumstances, the applicant's failure to meet any requirement, whether numerical or otherwise, is such that exercise of the privileges of the licence applied for is not likely to jeopardize flight safety;



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b) relevant ability, skills and experience of the applicant and operational conditions have been given due consideration; and

c) the licence is endorsed with any special limitation or limitations when the safe performance of the licence holder's

duties is dependent on compliance with such limitation or limitations.

2) Confirm that procedures for coordination between medical assessors, other subject matter experts (SMEs) and Licensing Authority are established.



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- 3) Review minutes of medical review/board meetings to confirm consultation with SMEs, operations department, etc.**
- 4) Review reports including analysis of loss of licence due to medical reasons and trend analysis of findings of the outcome of the medical certification.**
- 5) Review policy, procedures and evidence of communication for the justification and outcome of the medical certification decision with the Licensing Authority, the applicant and the relevant medical examiner.**



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PQ 3.421 CE-5

Has the State implemented a process describing circumstances under which a medical examination may be deferred?

- 1) Confirm that the process developed and implemented complies with the regulations.**
- 2) If the policy formally adopted by the State is that the medical examination cannot be deferred, the PQ is “Not Applicable”.**
- 3) If deferred, review the frequency and reasons for deferral.**



PQ 3.422 CE-6

If the State authorizes its national licence holders to **perform their medical examinations in a foreign State**, has a system been implemented to ensure:

- a) the proper and **valid designation of the foreign medical examiners**; and
- b) the proper **surveillance of the foreign medical examiners**?



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- 1) Check the system in place.**
 - 2) Check if foreign authorities are contacted or if they make available sufficient information.**
 - 3) Check the system for receiving and assessing medical reports and if said system is carried out by the foreign authority.**
- reports of DMEs and analysis of outcomes of medical assessments.**



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- 4) Check if there is a system to ensure that an **overseas DME is properly designated, trained and in good standing** with the overseas Licensing Authority.
- 5) Review evidence to ensure effective implementation, e.g. list of foreign DMEs and medical assessors, audit



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PQ 3.423 CE-6

If the State has not established any system for assessing the medical fitness of licence applicants and licence holders, has the State implemented practices and procedures to ensure the medical fitness of an applicant **(e.g. the validation of a foreign medical assessment)**?

1) Evaluate procedures and practices implemented for the validation or conversion of foreign medical assessments.



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2) Review evidence to confirm effective implementation, e.g. number of foreign validations, States where such medical assessments are issued, analysis of loss of certification due to medical reasons and trend analysis of findings of the outcome of medical certification.



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PQ 3.451 CE-5 PPQ

Has the State established a procedure for the designation of medical examiners and provided **guidance material to them?**

Description of the system and criteria for the designation of medical examiners:

- 1) conditions and duration of the designation;**
- 2) scope of authority given to a medical examiner (e.g. issuance of waivers, classes of medical assessment, etc.);**



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- 3) guidelines provided to the medical examiners (e.g. template reports, manual for the medical assessment, etc.); and**
- 4) methods for informing medical examiners of new medical-related provisions.**



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PQ 3.453 CE-6 PPQ

Does the State require designated medical examiners **(DMEs)** to demonstrate their **competency** in aviation medicine before designation?

- 1) Review the procedure for designation of medical examiners.
- 2) Verify that, before initial designation, the DMEs:
 - a) undergo the required training and demonstrate adequate competency in aviation medicine; and
 - b) have practical knowledge and experience of the conditions in which the holders of licences and ratings carry out their duties.



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3) Review evidence to confirm effective implementation

a) check publication of DME list; and

b) review DMEs files and records.

Note to the auditor:

Examples of practical knowledge and experience are: flight experience, simulator experience, on-site observation and any other hands-on experience deemed to be valid by the Licensing Authority.



PQ 3.457 CE-6

Does the State ensure that designated medical examiners (DMEs) attend **refresher training** in aviation medicine at regular intervals?

- 1) Review procedures for renewal of designation.
- 2) Verify that, before the renewal of designation, the DMEs undergo refresher training with intervals of **3 to 5 years**. (Training or seminar organized by the State or by other States or recognized organization.
- 3) Sample DME files.
- 4) Review evidence to confirm effective implementation.



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PQ 3.459 CE-7

Has the State implemented a system for the **supervision and control of designated medical examiners (DME)?**

- 1) Description of the oversight system for DMEs.**
- 2) Verify inclusion of premises and equipment inspections.**
- 3) Demonstration of use of latest ICAO SARPs.**
- 4) Up-to-date refresher training.**



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5) Timely transmittal of reports to Licensing Authority's medical department.

6) Review evidence to confirm effective implementation, e.g. oversight reports, audit reports, training records, designation documentation, etc.



PQ 3.461 CE-8

What action does the Licensing Authority take in the event that sufficient evidence exists to demonstrate that a designated medical examiner **(DME) has not performed his/her duties** in accordance with the prescribed procedures?

- 1) Review enforcement system and/or procedures.
- 2) Review evidence to confirm effective implementation of a graduated response system (warnings, sanctions).



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PQ 3.463 CE-6

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.**



SMS in medical examination- Annex 1

1.2.4.2 States shall apply, as part of their State safety programme, **basic safety management principles to the medical assessment process of licence holders that as a minimum include:**

- a) routine analysis of in-flight incapacitation events and medical findings during medical assessments to identify areas of increased medical risk; and**
- b) continuous re-evaluation of the medical assessment process to concentrate on identified areas of increased medical risk**



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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.

**Detailed Guidance-
Medical manual Doc 8984**



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Important USOAP dates for APAC

- **9-16 April 2025 ICVM PNG**
- **4-11 June 2025- ICVM Cambodia**
- **11-23 June 2025 USOAP CMA- Maldives**
- **9-22 July USOAP CMA- New Zealand**
- **27 Aug- 8 Sept 2025- USOAP CMA Thailand**
- **2026 USOAP plan EB in June 2025 for updates**
- **March 2025 Philippines-postponed for next date**



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Discussion

- **Practical consideration during USOAP activities on MED issues**
- **Who leads?**
- **Confidentiality**
- **Audits of report**
- **SMS principle**
- **Data reporting**



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Further reference

- **Annex 1**
- **Personnel Licensing Manual Doc 9379**
- **Medical Manual Doc 8984**



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THANK YOU

