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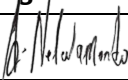
QUALITY MANAGEMENT SYSTEM

Process – Approval of Medical Practitioners

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Approval

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Distribution

Name	Means of Distribution
All SAMSA Staff	Internal Communications
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Revision History

Version	Date	Summary of Changes
1.0		First Issue of the Guidance Note

Document Review

Version no. - Date	Document	Reference
Ver. 1.0 – 19/04/2021	Accreditation of Medical Practitioners	QMS-OG-1003.1

Introduction

1. This procedure provides detailed requirements for the Approval of Medical of Medical practitioners to conduct medical examination of seafarers as required by the Merchant Shipping (Eyesight and Medical Examination) Regulations, 2004, as amended
2. These requirements are compulsory and the Examiner conducting the review, assessment and inspections as set out in this procedure shall ensure that each Medical Practitioner or group of Medical Practitioners shall meet all the requirements or provide suitable alternative

Scope

3. The requirements of this Procedure applies to all medical practitioners, individually or as a group, who seek to be so approved to conduct seafarer medical Examinations as required by the Merchant Shipping (Eyesight and Medical Examination) Regulations, 2004, as amended.

Requirements

Qualifications and Experience

4. The Medical Practitioner must meet the following requirements, viz;
 - 4.1. Must hold a valid registration as a Medical Practitioner on the Medical and Dental board of the HPCSA,
 - 4.2. Must:
 - 4.2.1. a postgraduate qualification in Occupational Medicine; or
 - 4.2.2. have completed at least one year experience as a ship's doctor, or
 - 4.2.3. 3 years as a 'shipping company' doctor, or
 - 4.2.4. 3 years under the supervision of a medical practitioner approved under these Regulations
 - 4.3. Shall have demonstrable knowledge of the requirements for **QMS-OG-1003.xx - Guidelines on the medical examinations of seafarers** [previously GOP-538]
5. Medical Practitioners applying in accordance with paragraph 4.2.2 above shall provide Certificates of Discharge or appropriately completed Seafarers' Record Book

Version no. - Date	Document	Reference
Ver. 1.0 – 19/04/2021	Accreditation of Medical Practitioners	QMS-OG-1003.1

6. Medical Practitioners applying in accordance with paragraph 4.2.3 above shall provide a 'testimonial' of their involvement with seafarers and ships from the appropriate shipping manager or superintendent.

7. Medical Practitioners applying in accordance with paragraph 4.2.4 above shall provide a 'Testimonial' from the approved Medical Practitioner detailing the applicant's involvement with seafarer medical examinations during the said period, including a record of all seafarer medical examinations which the applicant.

8. Provision of training by the approved Medical Practitioner towards a testament in paragraph 7 above does not compromise the quality and the outcomes of the Medical Examination and shall issue all the certificates.

9. Medical practitioners shall be independent of employers. Approved Medical Practitioners associated with employers under the requirements that existed immediately before this requirement may be permitted to continue until their approval expires.

Requirements for the Medical Practice

10. The Medical Practice may not be in a home, unless such a home has been designated as a place of business by the relevant authorities (municipality).

11. The practice shall have the following:

11.1. the practice shall be registered with the appropriate national health authority as a medical facility and comply with appropriate legislation

11.2. efficient reception arrangements, adequately furnished.

11.3. a properly equipped consulting room, with at least the following amenities

11.3.1. toilet and hand washing facilities in the consulting room

11.3.2. arrangements for urine sampling which are discreet, clean and which do not involve samples being carried through patient areas

11.4. Examination equipment including:

11.4.1. screens or curtains for privacy

11.4.2. normal clinical examination tools

11.4.3. fixed height measure

11.4.4. approved and verified weighing scales for clinical use

Version no. - Date	Document	Reference
Ver. 1.0 – 19/04/2021	Accreditation of Medical Practitioners	QMS-OG-1003.1

- 11.5. arrangements for immunisation, audiometry and fitness testing [may be offsite, however – readily accessible]
 - 11.6. schedules and records for servicing and calibration of all equipment
 - 11.7. public liability insurance and appropriate professional indemnity
12. No mobile health facility may be approved for conducting seafarers’ medical examination.
13. Approved Medical may not conduct Seafarers Medical Examination offsite, where such is necessary, may only be permitted, prior to such examination taking place, under the following conditions;
- 13.1. To examine seafarers who are signed on to the ship, this shall be under extreme circumstances where the seafarer(s) may not be permitted to come ashore; or
 - 13.2. To examiner seafarers in remote areas of the republic where there are no Approved Medical Practitioners.
14. Each Medical Practitioner, or a Group of Medical Practitioners, shall be approved in a single address, where a second address is required to be approved, this facility must be equipped in accordance with the provisions on this procedure and shall be subject to inspection (will be listed as secondary venue).
15. Where change of address is necessary, no medical examination shall be conducted in the new venue until such venue is inspected and approved accordingly.

Record Keeping

16. Approved medical practitioners shall have a systematic methods of keeping records within the facility. Records of Seafarer medical examination shall be kept for a minimum period of at least 10 years. Such records shall be such that:
- 16.1. They are easily accessible for the purpose of audit by SAMSA official or any other person so authorised;
 - 16.2. They may be used to confirm the verification requests from SAMSA as well as employers, such verification shall only confirm the authenticity and content of the Medical Certificate

Version no. - Date	Document	Reference
Ver. 1.0 – 19/04/2021	Accreditation of Medical Practitioners	QMS-OG-1003.1

17. Records shall, so far as is possible and practical, be kept using electronic methods, where records are kept in electronic format with appropriate protection(s) are in place. Such system shall:

17.1. record the following information – first name, surname, DOB, gender, ID number (PP for foreign nationals), medical certificate number, examinations outcomes, and any other fields necessary for good record keeping;

17.2. provide quick access to seafarer records using any of the fields referred to above;

17.3. include scanned documents generated from conducting the seafarers' medical examinations

18. Approved Medical Practitioners shall submit monthly returns of completed seafarers medical examinations via e-mail to ddddddd@samsa.org.za, such returns shall be in an excel file as set out in **QMS-OF-1003.xx – Seafarers medical examinations**, together with scanned copies of the medical certificate

Approval procedure

19. The application shall be accompanied by all the documents as set out in **QMS-OC-1003.1 – Checklist for submission of information**.

20. The SAMSA Examiner charged with the approval will assess compliance with the documents as set out in paragraph 19 above and the subsection dealing with **Qualifications and Experience**, no further actions will be taken unless those requirements are met.

21. The Examiner shall continue to have a meeting with the Medical Practitioner, during such meeting, the SAMSA Examiner shall establish the following:

21.1. Verify the identity(ies) of the applicant Medical Practitioner

21.2. Enquire about the Seafarers Medical Examination process

21.3. Establish the understanding that the Medical Practitioner has of **QMS-OG-1003.xx - Guidelines on the medical examinations of seafarers**

21.4. To be familiarised with the facility and other persons involved in the process

22. The meeting shall immediately be followed by the inspection of the medical practice, the Examiner shall establish compliance with the **Requirements** subsections on **Requirements for the Medical Practice** and **Record Keeping**.

Version no. - Date	Document	Reference
Ver. 1.0 – 19/04/2021	Accreditation of Medical Practitioners	QMS-OG-1003.1

23. The requirements of paragraphs 21 and 22 above shall be recorded in '**QMS-OC-1003.2 – Audit Checklist and Aide Memoir**' and the Audit section below.

Quality Assurance and Auditing

24. SAMSA has adopted the ISO 9001:2015 Quality Management System (QMS) for its activities under the Merchant Shipping (Eyesight and Medical Examination) Regulations, 2004, as amended and as such, all Medical Practitioners are subject to auditing in accordance with the QMS principle.

25. The Medical Practitioners will be audited under the following circumstances:

25.1. During the approval process;

25.2. During an adhoc Audit;

25.3. During an investigation when there are complaints from Seafarers and other interested parties.

26. The Objectives of Auditing in paragraph 25.2 above are, can be applied together or individually, as follows:

26.1. To monitor the application of the Medical Standards by Approved Medical Practitioners;

26.2. to investigate the effectiveness of the administrative arrangements employed by Approved Medical Practitioners

26.3. to provide information into the SAMSA continuous improvement

27. The audit as set out in paragraph 25.2 above, may inspect some or all of the following areas:

27.1. The Qualifications and Registrations with the HPCSA, being valid at all times;

27.2. That facilities are maintained in a good state of repair, as set out in **Requirements for the Medical Practice** subsection

27.3. Administrative arrangements, viz

27.3.1. Comparing the returns submitted in accordance with paragraph 18 above with the information on record at the Medical Facility

27.3.2. Records are kept confidential and access is limited to persons authorised to do so

Version no. - Date	Document	Reference
Ver. 1.0 – 19/04/2021	Accreditation of Medical Practitioners	QMS-OG-1003.1

28. The SAMSA Examiner shall provide brief outcomes of the Audit before leaving the Medical Facility, where there are findings – the Approved Medical Practitioner shall be informed of the requirements to make good the defects.

29. The examiner shall complete a **QMS-OF-1003.xx – Report of Adhoc Audits of Approved Medical Practitioners**, a copy which shall be provided to the Medical Practitioner through e-mail means. The medical practitioners has 30 days to make good any findings made there (a copy shall be provided to the Senior Examiner responsible for the Office).

Suspension and cancellation the Approval

30. The approval of a Medical Practitioner may be suspended and/or cancelled on non-compliance with one or more requirements set out in the Merchant Shipping (Eyesight and Medical Examination) Regulations, 2004, as amended

31. The Principal Officer, on suspending and/or cancelling an approval of a Medical Practitioner, shall do so using **QMS-OF-1003.xx – Notice of Suspension or Cancellation of Approval for Medical Practitioner** and provide the medical practitioner with grounds for such action.

32. Where the Medical Practitioner(s) has been issued with a suspension, such notice include an intention to cancel the approval. The Principal Officer may, after 30 days of issuing a Notice of Suspension, issue a Notice of Cancellation.

33. The Medical Practitioner(s), upon receiving such notice, shall make good on findings or make representations, as is necessary, to the Principal Officer.

Medical Certificates Forms and Returns

34. Upon approval, each Medical Practitioner shall be issued with a single set of the Seafarers' Medical Certificate forms, which are serialised for auditing purposes. Medical Practitioners who share facilities may share their forms

35. Each form is provided in triplicate, such that:

35.1. The cover form is the original certificate issued to the Seafarer

35.2. The yellow form is due for return to SAMSA

35.3. The green form is for the Medical Practitioner's records

36. Medical Practitioners who run out of forms may purchase these from their nearest SAMSA Office

Version no. - Date	Document	Reference
Ver. 1.0 – 19/04/2021	Accreditation of Medical Practitioners	QMS-OG-1003.1