Sjøfartsdirektoratet
Norwegian Maritime Authority

Circular - Series V

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☒	Sdir :	The Norwegian Maritime Authority
☐	A:	16 specially authorized employment offices
☐	U:	Selected Foreign Service stations
☐	P:	Equipment manufacturers, any subgroups
☐	OFF:	Offshore companies/platform managers/operators
☐	Hov:	Main organizations
☒	Others:	Seafarer's doctors establishing/having a quality system

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Quality system for seafarer's doctors

Pursuant to the Regulations of 5 June 2014 No. 805 on the medical examination of employees on Norwegian ships and mobile offshore units (Health Regulations), seafarer's doctors are required to have a quality system ensuring that the work is carried out in accordance with the requirements of the Health Regulations. The quality system shall be in accordance with a internationally recognised standard, cf. section 7 first paragraph (h) of the Health Regulations.

The purpose of this circular is to show the minimum required content of such a quality system for seafarer's doctors. The circular is based on principles from international standards for quality systems, but is not complete with regard to the respective requirements in the different standards.

The Health Regulations entered into force on 1 July 2014, and doctors who were approved as seafarer's doctors at this time are covered by the transitional arrangement of section 19 of the Regulations, and must therefore implement a quality system by 1 July 2019. Doctors not approved as seafarer's doctors when the Regulations entered into force will have to implement a quality system before they can be approved as seafarer's doctors.

Approved seafarer's doctors shall apply for renewal of the approval every five years. The form "Self-declaration – quality system for approved seafarer's doctor" shall be enclosed with the application.

If the quality system is changed/replaced for any reasons, a new self-declaration form shall unsolicited be submitted to the Norwegian Maritime Authority (NMA).

Supervision

The NMA carries out risk-based supervision of the seafarer's doctors. The supervision may be unscheduled or announced in advance. The NMA will in particular check that the minimum requirements, as listed in the next paragraph, are included in the seafarer's doctor's quality system.

Minimum required content of a quality system for seafarer's doctors

The main principle of a quality system is that the company shall develop, deliver and improve products and services in accordance with both specified requirements and expectations. The quality system shall clarify how the company is organised and managed in order to meet both external and internal quality requirements and expectations.

The requirement stipulated in the Health Regulations is that the seafarer's doctor shall have a quality system in accordance with an internationally recognised standard. This could for instance be a system based on ISO 9001 or IMHA Quality.

The seafarer's doctor is not required to have the quality system certified, but the doctor must in connection with the application for approval be able to document, by filling out the self-declaration form, that a quality system has been implemented. It is up to the individual doctor to find the standard best suited for his or her practice, and to decide how to obtain and implement their quality system. One way of doing this is to become certified by a third party such as DNV or IHMA Quality, another is to create their own quality system based on an international standard, such as ISO 9001.

When the NMA carries out supervision, the seafarer's doctor must demonstrate that the quality system is functioning. The seafarer's doctor must be able to account for their administrative procedure, including medical decisions.

Minimum requirements for elements to be included in a seafarer's doctor's quality:

1) Quality manual

The seafarer's doctor must develop and maintain a quality manual for quality management and the documented routines which have been established. The following paragraphs concretise the contents of a quality manual.

2) Quality policy

The seafarer’s doctor must enter the quality goals he or she has for the work as a seafarer's doctor in the quality manual. An example of a quality goal is: "The practice as seafarer's doctor shall be carried out in accordance with the Health Regulations, the Public Administration Act and sound medical judgement."

3) Normative documentation

The seafarer's doctor must identify the documents, both internal and external, which are normative for how he or she shall operate as a seafarer's doctor. The quality manual is a typical internal normative document, whereas laws and regulations are typical external normative documents.

The quality system shall show the requirements applicable to seafarer's doctors and their products, i.e. medical certificates and declarations of unfitness. The Health Regulations, the guide to the Regulations and the Public Administration Act are examples of external normative documents which concretise such requirements. For doctors in Norway, another such normative document will be the Health Personnel Act.

A documented routine for the control of normative documents shall be established, in order to:

- approve the adequacy of documents before they are published
- review and, if necessary, update and reapprove documents
- ensure that amendments of current documents are made evident
- ensure that the correct version of relevant documents are available where they are being used
- ensure that documents are readable and easy to identify
- ensure that documents with external origin, which the seafarer's doctor has decided are necessary for the planning and operation of the quality management system, have been identified, and that the documents are being distributed to the relevant recipients (seafarer's doctors and any other employees forming part of the administrative procedure)
- prevent unintentional use of out-dated documents, and apply the use of appropriate identification (e.g. mark the document with "expired version") for documents which are to be kept for a specific purpose, so that they are not confused with current applicable documents.

4) The main processes of the practice

The main processes of a seafarer's doctor's practice are listed below. The following supplementary points are important to take into consideration. (Note that the list is not exhaustive, there may also be other processes carried out by the seafarer's doctor, which must be identified and described.)

Medical examination of employee

- Is the basis for the decision sufficiently documented in the medical record?
- Is the medical documentation sufficient?
- Have the right supplementary examinations been carried out?
- Has a statement from specialist been requested, if necessary?
- Has purchasing competence been documented in the referral letter to the specialist, by requesting assessment of relevant factors?
- Is there sufficient epidemiological knowledge of the employee's condition, and has the likelihood for complications and other medical events associated with the condition been correctly assessed?
- Has the likelihood for an event occurring during the certificate period been individualised, based on the employee's type and degree of a medical condition, compared to the group of individuals with the same condition?
- Has a "best practice" assessment been made of the likelihood for a medical event occurring?
- Has the employee's duties, tasks and working situation been taken into account?
- Have the consequences of a medical event occurring in the employee's working situation been assessed, and has a risk assessment been carried out thereof?

- Has a risk evaluation been carried out in accordance with the Guide to the Regulations (likelihood x consequence)?
- Have compensating measured been assessed?

Issue of medical certificate

- Has the employee been informed in writing of the grounds for the decision?
- Has the employee been informed in accordance with the Public Administration Act of the possibility to appeal the seafarer's doctor's decision or to apply for an exemption?

Issue of permanent, temporary or provisional declaration of unfitness

- Has the employee been informed in writing of the grounds for the decision?
- Has the employee been informed in accordance with the Public Administration Act of the possibility to appeal the seafarer's doctor's decision or to apply for an exemption? (Note: it is not possible to apply for exemption in the event of a provisional declaration of unfitness.)

A description of the main processes and their interrelation shall be included in the quality manual.

5) System for non-conformance reporting and improvement suggestions

The seafarer's doctor must have a system for the treatment of non-conformance. The system shall record non-conformities so that corrective actions can be implemented and registered, and the system shall also include an overview of preventive measures.

A non-conformity in the practice as seafarer's doctor will typically be feedback given to the seafarer's doctor demonstrating that the decision he or she made had a material (medical) or procedural (non-compliance with the Health Regulations or the Public Administration Act) error. Failure to check the employee's ID will for instance be a procedural error, which will result in the issued medical certificate being invalid. If the seafarer's doctor is made aware of this error, he/she will first of all have to implement corrective measures (invite the employee to a new examination and issue a valid medical certificate). The seafarer's doctor must then consider which preventive measures to implement in order to avoid such incidences in the future. Procedures shall be established for non-conformance treatment, corrective measures and preventive measures. If appropriate, these procedures may be gathered in one common procedure.

6) Requirements for registrations

As part of the quality system, the implementation of the below points must be recorded with traceability. The registrations may e.g. be made in a log or in a report of the activity (in a Word document, on a paper, etc.; there are no formal requirements other than the registration being in writing).

- Competence and training
  - The Health Regulations require the seafarer’s doctor to complete a course in maritime medicine. The completion of the course and other forms for competence enhancement as seafarer's doctor or for other employees shall be

recorded.

- Identification and traceability
  - The decisions made by the seafarer's doctor shall be traceable and identifiable. This shall be ensured through the new electronic administrative system for medical certificates and declarations of unfitness. For other documents, such as medical examination forms and medical records, the seafarer's doctor must describe how these are stored and made traceable, e.g. by means of a filing system. This will normally be regulated by national health legislation.

- Calibration and verification of measuring equipment
  - It must be stated in the quality manual how the seafarer's doctor ensures the proper functioning of the equipment used.

- Corrective/preventive measures
  - When a non-conformity has been registered, the seafarer's doctor must make a memo of how the non-conformity was rectified, and how this non-conformity is being followed up in order to prevent the same non-conformity from reoccurring.

- Internal audit / management review
  - The seafarer's doctor or other person in the management must regularly review and evaluate the quality system, in order to ensure its proper functioning.
    A report shall be made of internal audits / management reviews.

A documented routine shall be established in order to stipulate the control necessary in order to identify, store, protect, retrieve, maintain and delete registrations. Registrations shall be readable and easy to identify and retrieve.

7) Internal audit / management review

The seafarer's doctor shall carry out internal revisions at least once a year, in order to determine whether the quality system is in accordance with the requirements for the practice, and whether the system has been efficiently implemented and maintained.
The management / seafarer's doctor shall in addition review the quality system in order to identify and implement measures to strengthen the system.
A routine for the planning and execution of internal audits / management reviews shall be established and documented.

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