

C.18018/14/2018-MH-II  
Government of India  
National Council of Secretariat  
Dte.GHS, Ministry of Health and Family Welfare (MoHFW)

Nirman Bhawan, New Delhi.  
Dated: 23<sup>rd</sup> January, 2020

24<sup>th</sup>

**MINUTES OF MEETING**

The minutes of the meeting “to consider amendment in the Gazette Notification of Government of India in respect of the Clinical Establishments (Central Government) Amendment Rules, 2018, dated 21.05.2018, especially with respect to the Authorised Signatory in Medical Diagnostic Laboratories” held under the Chairmanship of DGHS on 14.01.2020 at Nirman Bhawan, New Delhi, are enclosed herewith for information.

*Anil Kumar*  
24-1-2020

Dr. Anil Kumar  
Addl.DDG

Tel: 011-23061329

**To**

1. The Participants as per the list annexed

**Copy for information to:**

1. Sr.PPS to DGHS
2. PPS to PC(PG)
3. PS to JS(MKB)
4. PA to US, MS division

**Minutes of the meeting held under the Chairmanship of DGHS on 14.01.2020 at 10.30 AM in  
Resource Centre, Room No.445-A Wing, Fourth Floor, Nirman Bhavan, New Delhi**

A meeting was held under the Chairmanship of Dr. Rajiv Garg, DGHS on 14.01.2020 at 10.30 AM in the Resource Centre, Room No.445-A Wing, Fourth Floor, Nirman Bhavan, New Delhi, to consider amendment in the Gazette Notification of Government of India in respect of the Clinical Establishments (Central Government) Amendment Rules, 2018, dated 21<sup>st</sup> March 2018, especially with respect to the authorized signatory in Medical Diagnostic Laboratory Reports.

List of participants is annexed.

After welcome and introduction, **Dr. Rajiv Garg, DGHS** informed that today's meeting has been called to bring about a consensus on the Minimum Standards to be followed in provision of Medical Diagnostic Laboratory Services within the current legal framework and various Courts Orders. He called upon participants that they may appreciate that it is highly important to implement Standard based laboratory care in order to provide accurate lab reports so that Clinicians can make the correct diagnosis of the medical condition and are able to deliver the required Medical care to the patients. The implications of wrong reports are very serious in nature.

**Dr. Anil Kumar, Addl.DDG**, made a Power-Point Presentation incorporating the following:-

Purpose and main provisions of the Clinical Establishments Act, 2010 (CEA), current situation of laboratory work in Government Sector and interpretation of Gazette Notification dated 21.05.2018. He informed that following two issues are there for consideration by this Committee:

1. Direction by the Hon'ble High Court of Jaipur, vide its Order dated 30.05.2018, wherein it is mentioned that "why the minimum qualification were not prescribed for the Basic Composite Laboratory in the Notification". Further order dated 06.11.2019 has directed this Ministry to finalize and publish the Notification (i.e., if amended) within three months, i.e., by 06.02.2020.
2. As per the Order of Hon'ble High Court of Delhi dated 26.11.2019, Ministry shall decide the representations of various associations in the court cases within the time allowed by the Jaipur High Court.

He also informed the processes involved including chronological sequence of events before and after the publication of the Gazette Notification dated 21.05.2018. The Court Orders existing at that time, especially the Delhi High Court Order dated 15.09.2017 and Supreme Court Order dated 12.12.2017, and opinions of various stakeholders including public comments received were considered while finalizing the Notification. He highlighted that as per the order of Delhi High Court dated 15.09.2017, medical report is a medical certificate, as provided under the Indian Medical Council Act, 1956.

He further informed about the provision of the Indian Medical Council Act, wherein only the medical practitioner registered with MCI or State Medical Council is authorized to sign the medical certificate. Under PCPNDT Act, medical geneticists having medical qualifications or PG degree in Biological Sciences are allowed to conduct tests related to Pre-Natal Diagnostic Techniques but no where it is mentioned that they can sign the report. Under Drugs and Cosmetics Act, drug testing is allowed by those holding PG Degree in medicine/Pharmacy/Sciences. He interpreted that the drugs testing may not be considered as a medical diagnostic report. He informed about the key provisions under Delhi High Court Order dated 15.09.2017 and Hon'ble Supreme Court Order dated 12.12.2017 and subsequent stand of Board of Governors in supersession of MCI, wherein it has explained the Supreme Court Order and endorsed and informed about the Government Gazette Notification dated 21.05.2018.

**After presentation, DGHS invited comments from the participants, the main points of which are summarized as under:**

**Dr. Ajay Soni, ACBM** stated that the convention of signing the Lab Reports, which was in practice in the Country before May, 2018, has not been followed in drafting of the Notification. There was no regulation prior to the Gazette Notification in this regard. PCPNDT, Drug & Cosmetics Act which are Acts of MoHFW allow equal status to the Non-Medical Post Graduates in Sciences. In many other Countries also, the non-medical Lab Scientists are holding the posts of Lab Directors and also signing the Reports. He stated that their association has no issue of their members being called as Technicians as mentioned in the Judgment dated 15.09.2017 of the Hon'ble High Court of Delhi.

**Dr. Neetu Khurana** informed that only doctors are answerable in respect of lab reports to Consumer Court, Medical Council and other Courts. PhDs have the capability to carry out the tests related to their respective topics/fields only, there is no regulatory body for them and they are not answerable in the Courts.

**Dr. Subrata Sinha** stated that anyone who conducts the test is also liable, as in many tests the non-medical person is also the Professional In-charge. Why should the doctors want to be responsible for the work done by the Scientist/Technicians.

**Dr. B.C. Koner** informed that the provisions of Civil and Criminal Negligence apply only to Doctors and not to non-medical persons.

**Dr. Uma Kanga** said that they do not give any opinion or make any diagnosis in respect of the tests conducted by them. They report only for the work done by them. Gazette Notification has ignored the competency of M.Sc./Ph.D. Scientists. While during the selection process, even in UPSC and AIIMS, the members of their association have been considered equal to medical doctors.

**Mr. Devesh Deval** informed that we should not justify the quackery and dilute standards. It is wrong to state that there was no regulation before the CEA, as IMC Act is an old Act and it clarifies that only a MBBS Doctor, registered under IMC Act can sign any medical certificate. Lab report is also a medical certificate. Specialist/Super-Specialist Doctors are there for opinions in their respective specialities. There is shortage of medical teachers in the country and to meet the same, the M.Sc./Ph.D. is allowed only to a limited extent. We have to have the systems and standards in place all over the country. Initially people with MSc. Biochemistry, Microbiology were accommodated as a good will gesture in Medical Colleges in MCI – “Point was objected by the non-medical participants”. He further stated that we should have system approach for regulation of various aspects of Labs and ensure implementation of the same. It is true that the system for regulation of non-medical persons in the Labs needs attention.

**Dr. R. K. Vats** stated that those doctors and non-medical Lab Professionals who have passion to serve the country, should own up what they are doing. Lab reports should be written clearly and scanned signatures should not be used on the reports. He also emphasized that each Laboratory personnel is entitled to do his/her work and own it. Further he mentioned that it is preferable that the reports are signed in ink/pen, so that the responsibility is identified. He said that we all are in Medical Profession and should not go to Courts for each and everything. He further informed that MCI has, after discussions, arrived at a consensus on this issue and it will be shared with the Dte.GHS/ Ministry officially.

**Dr. Smita Mishra** said that there is no distinction between two categories of Lab Personnel, i.e., medical and non-medical, in many foreign countries. Standards of training should be prescribed and competency testing should be done. A Board should be constituted for that purpose.

**Dr. V.K. Gupta** stated that those who do M.Sc/Ph.D courses from Medical Colleges, are exposed to the patient care during their training and such non-medical personnel may be considered for allowing them to sign the lab reports.

**Dr. Rohit Jain** raised the point that independent signing by the non-medical persons shall be in violation of the Order of the Hon'ble Supreme Court of India and the Court had already dismissed a review petition in this regard. He further stated that every report needs interpretation and there is nothing like technical report in the medical field.

**Dr. Chand Wattal** stated that there is no term referred to as Technical Report in medical field, e.g., in tests like HIV Testing, where the report is given as either positive or negative, it has serious implications, if wrong reporting is done. Only a Doctor is competent to give such report, as a medical expert will issue such a report after reconfirming the test and post – test counseling. There is no technical report involved here.

**Dr. R.N. Tandon** said that Non-medical persons cannot be regulated under MCI, so if they are to be involved they should be brought under regulation by constituting a Council. There is no such report available about deficiency of doctors in the Country on the ground. He also mentioned that the qualified doctors are not getting jobs. Government is already allowing Non-MBBS doctors to get involved in Medical domain in full strength, which is hampering the career of MBBS Doctors. MBBS Doctor is responsible to the patient and answerable to authorities and Courts. The Government should consider the whole scenario, considering the benefits and welfare of the patients.

**Dr. Promila Gupta** raised an issue of shortage of Man Power and Infrastructure to check and countercheck each and every report for its authenticity. **Dr. Rohit Jain** replied that the ground of shortage of Man Power and Infrastructure is not admissible in a Court of Law. **Dr. B.C. Koner** stated that giving liberty to non medical persons to issue and sign the lab reports will lead to mushrooming of Labs run by unregulated personnel in the Country. A regulatory body is required before permitting non-medical persons.

**Dr. Ajay Soni**, said that they are ready to be regulated and they have already made a demand for creation of a Regulatory Council for the members of their associations. **Dr. N.K. Mehra** and **Dr. Uma Kanga** endorsed his view.

**Dr. Vandana Jain** stated that competency testing of laboratory personnel should be done like it is being done under NABL Accreditation Program.

**Dr. Vikas Manchanda** informed that the health workers are allowed to conduct tests after receiving intensive training, and ASHAs are conducting screening tests only. Further the health workers work under the supervision of Primary Health Center (PHC) Medical officer who is a MBBS doctor. Laboratory Science is an established branch of medicine and advancements in this field are happening every day. There is no term like technical report and Lab report is only of one type, which contains interpretation. The report, like urine culture, has to be reported in the context of patient and antibiotic sensitivity is required to be tested as per the organisms grown on culture. Only medical doctors possess such knowledge. Similarly, simple test like Haemoglobin has to be reported in terms of counts of RBCs, WBCs. M.Sc./Ph.Ds are trained only in a focused area and have no exposure to patient care. First a system of certification and regulation should be developed before including the non-medical personnel.

**Dr. Ritu Singh** stated that the Lab Reports have to be in co-relation with clinical condition of patients. MBBS should be made essential in Basic Laboratories.

**Dr. Subrata Sinha** said that by boycotting the Scientists with M.Sc./Ph.Ds Qualification, progress of Laboratory Science will stop, as only Scientists bring about advancements in the field.

**Dr. K.L. Ramesh** informed that in NCDC and Vector Borne Program, non-medical laboratory scientists are signing the lab reports. He was also earlier HOD of Biochemistry Department of Dr. RML Hospital and in that capacity he was signing all the reports despite being from non-medical background. No issue of wrong reporting arose at any point of time, during his tenure at Dr. RML Hospital, New Delhi.

**Principal Consultant, Dr. Promila Gupta** concluded the meeting with a request to the participants to send their additional comments, if any, by 17<sup>th</sup> January, 2020 positively.

The meeting ended with a vote of thanks to the Chair and participants.

**LIST OF PARTICIPANTS**

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