

Abstract

The object of this quality investigation program is to know, by means of onsite witness, whether the operating process, examination competence and quality assurance of foreign laborers' health examination of designated hospitals meet the requirements of CDC's draft regulations and accreditation in future. It also aims to help hospitals understand the contents and possible queries of the draft regulations and medical laboratory accreditation criteria, which is based on ISO 15189:2003 (Medical laboratories -Particular requirements for quality and competence).

Currently there are 68 designated hospitals for foreign laborers' health examination. This program randomly selected 15~20 designated ones out of 34, which have higher business volume in foreign laborers' health examination, and had them approved by CDC for conducting onsite investigation. The checklist included examination processes or movement routes, patient identification, specimen exchanging prevention, quality assurance and testing record. The assessor team was composed of quality experts, parasitologists, thoracic doctor and the officers from CDC and the Department of Health.

After the completion of evaluation, there are 4 hospitals, accounting for 24% in all investigated hospitals, being able to meet requirements of future regulations after correcting their non-conformance as advised by assessors. There are also 10 hospitals, 59% in all investigated hospitals, being able to meet requirements of future regulations after correcting their non-conformance and enhancing the on-job training. However, there are 24 hospitals, 11% in all investigated hospitals, found to be far away from meeting requirements of future regulations. In addition, there is one hospital, 6% in all investigated hospitals, which was only assessed by oral description and written paper instead of onsite witness of actual practices and examination due to no examination requesters on that day. Basically, that hospital maintains a good management system according to the instruction by the hospital accompanist; but we suggest that it shall concern more improvement in the examination process and the organization of testing accommodation.

Furthermore, there are 6 hospitals, 35% in all investigated hospitals, which meet the ISO 1589 criteria after conducting the improvement of management responsibility allocation, planning and execution of related quality assurance, calibration and maintenance of equipment, on-job training and competence monitoring of personnel, management of good housekeeping, and corrective actions of the non-conformance from the testing item. But, there is one hospital, 6% in all investigated hospitals, which is far away from meeting the requirements of ISO 15189 criteria. In addition, there are 10 hospitals, 59% in all investigated hospitals, setting up or will establish their laboratory quality system to meet the requirements of ISO 15189 criteria.

In conclusion, though there are a few problems to meet the regulations regarding accommodating the cost and the personnel operations management as informed by some hospitals, most designated hospitals have improved their management system and hopefully will meet the requirements of CDC's draft regulations after being acquainted with the new quality investigation program. Furthermore, they also hope more training courses in parasite examination, leprosy and laboratory accreditation will be provided by CDC in future in order to improve their testing competences.

Keywords : Medical laboratories-particular requirements for quality and competence ; the regulations on Employment and Management of Foreign Laborers ; laboratory accreditation