Accreditation of Medical Laboratories by Using ISO15189 in Taiwan: A Report of Fitness Investigation

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Accreditation programs are generally used as one of the tools for continuous quality improvement of medical laboratory in Taiwan. Among those developed accreditation programs, ISO 15189 is the most popular guideline for quality requirement in medical laboratories performance worldwide at present. However, there are still a lot of medical laboratories which have not been enrolled in this program. In order to know how ISO15189 works in Taiwan, the investigation was conducted. A questionnaire which is composed of 157 questions was designed based on ISO15189 guideline. Orientation (year 2005 from November to December) in seminar or inquiry on-site (Dec/2005) were used to carry out the questionnaire. Out of 645 questionnaires, 242 valid samples were collected, which equals to 37.5% of the data collected. According to conformability and executive condition of management and technique request, the results were: (1) Orientation in seminar results: In terms of management request, 25.1% were ≥80% (n=54), 16.7% achieved request 60% ≤X<80% (n=36) and 58.2% had<60% (n=125). On the other hand for technique request: 34.9% fit ≥80% (n=75), 34.4% were 60% ≤X<80% (n=74) and there were 30.7% had request <60% (n=66). Based on the overall requests, laboratories fit ≥80% of ISO15189 requirements were 25.1% (n=54), 33.5% were 60% ≤X<80% (n=72) and 41.4% were <60% (n=89). (2) Results of on-site visiting questionnaire: In terms of management request: 18.5% were ≥80% (n=5), 33.3% achieved request 60% ≤X<80% (n=9) and 48.2% had<60% (n=13). On the other part for technique request: 37.0% fit ≥80% (n=10), 40.8% were 60% ≤X<80% (n=11) and there were 22.2% had request <60% (n=6). Based on the overall requests, laboratories fit ≥80% of ISO15189 requirements were 22.1% (n=6), 33.3% were 60% ≤X<80% (n=9) and 44.5% were <60% (n=12). This outcome reveals that only 22~25% of medical laboratories fit 80% of ISO 15189 requirements. In short, there are executive difficulties taking ISO 15189 guideline as the regulation rule for laboratories management in domestic local community hospitals and commercial laboratories for the time being. Continuous education and consultation to improve medical laboratory quality should be emphasized presently before adopting ISO 15189 as the general rule of medical laboratory performance in Taiwan.

Key words: Laboratory accreditation, ISO 15189, Management requirement, Technical requirement

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