

Code of Practice: COP-02

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醫療儀器的規管



Regulation of
Medical Devices

Code of Practice
for
Conformity Assessment Bodies

Code of Practice: COP-02



中華人民共和國

香港特別行政區政府衛生署

Department of Health

The Government of the Hong Kong Special Administrative Region
of the People's Republic of China

Table of Contents

| | |
|---|---|
| 1. Introduction | 1 |
| 2. Requirements of CABs | 1 |
| 3. Monitoring of CABs..... | 4 |
| 4. Appeal against a Decision to Reject Changes of Scope of Recognition..... | 5 |
| 5. Cessation or Suspension of Recognition..... | 6 |
| 6. Appeal against a Decision of the MDCO to Cease or Suspend Recognition or against an Instruction of the MDCO | 6 |
| 7. Enquiries..... | 6 |

1. Introduction

- 1.1 Conformity assessment is one of the essential requirements under the Medical Device Administrative Control System (MDACS) to ensure that the medical device conforms to the Essential Principles of Safety and Performance of Medical Devices specified in GN-01.
- 1.2 The conformity assessment includes many elements including the Quality Management System, Post Market Surveillance System, Summary Technical Document and Declaration of Conformity. Each medical device shall be allocated to one of four classes using the Classification Rules for Medical Devices under GN-01. Class I devices are the lowest risk devices, Classes II are moderate to low risk, Class III are moderate to high risk and Class IV are the highest risk. The level of scrutiny, evidence requirements that the device meets the *Essential Principles of Safety and Performance of Medical Devices* under GN-01 and the conformity assessment procedures become more robust and demanding for higher risk classes of devices. The detailed requirements of the conformity assessment procedures are stipulated in the Technical Reference TR-001: *Principles of Conformity Assessment for Medical Devices*.

2. Requirements of CABs

- 2.1 General Requirements
 - 2.1.1 A CAB must be a legal entity having an office in Hong Kong.
 - 2.1.2 It shall be a Certification Body accredited for Quality Management System (QMS) by a member of the International Accreditation Forum (IAF).
 - 2.1.3 It must have adequate resources to provide conformity assessment services that fall within its scope of recognition. Its resources must be adequate in terms of its financial capability, equipment, staffing, competence and (in some cases) subcontractors.
 - 2.1.4 It must, prior to providing its client with conformity assessment services, sign an agreement with the client with the charge and conditions of the services explicitly specified.

- 2.1.5 It cannot subcontract or delegate its responsibility for the conformity assessment. It is allowed however to subcontract some of the checking, examination and audits that are part of the conformity assessment, but the CAB must monitor the performance of the subcontractor, review the results of any checking, examination and audits performed by the subcontractor, and determine the outcome of the assessment based on those results and the results of any additional checking, examination and audits performed by itself.
- 2.1.6 It shall make available to the MDCO upon request documentation about its financial situation.
- 2.1.7 It shall issue a certificate to the manufacturers complying with the MDACS conformity assessment requirements. The certificates shall be in Chinese or English or both and shall clearly specify all the makes and models covered.

2.2 Quality Records

The originals or copies of the following documents related to the conformity assessments shall be kept in the Hong Kong Office and be made available to the MDCO for inspection upon request:-

- (a) contracts/agreements between the CAB and its client;
- (b) contracts/agreements between the CAB and its subcontractors (if any);
- (c) records that can demonstrate the competence of the CAB's employees and subcontractors;
- (d) conformity assessment reports; and
- (e) conformity assessment certificates.

2.3 Disclosure of information to the MDCO

The CAB must ensure, when contracting with a client/subcontractor in connection with any conformity assessment activities under the MDACS, that the contract will **give the CAB permission to disclose to the MDCO any information that the CAB obtains or receives in the course of or in connection with the conformity assessment.**

2.4 MDCO Attending Audits

The CAB must ensure, when contracting with a client/subcontractor in connection with any conformity assessment activities under the MDACS, that the contract will allow staff from the MDCO to attend the audits conducted by the CAB or its subcontractors.

2.5 Obligations

2.5.1 The CAB, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer, user or LRP of the devices which they inspect, nor the representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the CAB.

2.5.2 The CAB and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications. Should the CAB subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets all the applicable MDACS requirements and, in particular any Guidance Notes and Code of Practice related to CAB. The CAB shall keep for the scrutiny of the MDCO the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor related to the MDACS.

2.5.3 The CAB must be able to carry out all the tasks for which it has been recognized, whether these tasks are carried out by the CAB itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. This presupposes the availability of sufficient scientific staff within the

organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been recognized, having regard to the MDACS requirements and, in particular, those set out in the *Essential Principles of Safety and Performance of Medical Devices* stipulated in GN-01. It must also have access to the equipment necessary for the verifications required.

2.5.4 The CAB must have:

- ✧ sound vocational training covering all the assessment and verification operations for which the body has been recognized;
- ✧ satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections; and
- ✧ the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

2.5.5 The impartiality of the CAB must be guaranteed. The remuneration must not depend on the results of the conformity assessment.

2.5.6 The CAB must take out appropriate liability insurance.

2.5.7 The staff of the CAB are bound to observe professional secrecy with regard to all information gained in the course of their duties.

3. Monitoring of CABs

3.1 Audits

A CAB is subject to the continual scrutiny of the MDCO and most of the scrutiny is in the form of audits. There are two types of audit, namely the surveillance audit and the witnessed audit as depicted in Table 1. The frequency of the audits will be determined by the MDCO on a need basis.

Table 1 - Surveillance and Witnessed Audits

| Type of Audit | Scope |
|--------------------|---|
| Surveillance Audit | Auditors from the MDCO will perform the following: <ul style="list-style-type: none">• To check that appropriate systems and procedures continue to be in place; and• To audit the CAB's operations and activities to verify that the MDACS requirements are complied with and to confirm the continuing effectiveness of the CAB. |
| Witnessed Audit | While the CAB is conducting an audit on a manufacturer's quality management system, auditors from the MDCO will be present in the audit, checking the CAB's related procedures and its compliance with the MDACS requirements. |

3.2 Investigations

In case of a complaint about or related to a CAB, a product recall or alert, a report of an adverse incident, etc., the MDCO may determine that it is necessary for it to initiate and conduct an investigation. The investigation may involve the MDCO inspecting the facilities and equipment of a CAB, inspecting and checking records being kept by the CAB, interviewing the CAB's staff or subcontractors, and any other appropriate checking by the MDCO, in all of which cases the CAB and its subcontractors must fully cooperate with the MDCO and, to the greatest extent they can, facilitate the conduct of the investigation.

4. Appeal against a Decision to Reject Changes of Scope of Recognition

Where a decision has been made by the MDCO to reject changes of scope of recognition under the CAB Recognition Scheme-

- ✧ the decision shall remain effective unless and until it is set aside in an appeal;
- ✧ an appeal against the decision lies to the CAB Recognition Appeal Board, but it must be lodged by the applicant in writing to the Board, c/o the Medical Device Control Office, within 4 weeks after the applicant is notified of the decision; and
- ✧ the Board's ruling in the appeal shall be final.

5. Cessation or Suspension of Recognition

Failure of a recognized Conformity Assessment Body to comply with any requirements of the Scheme, or with an instruction issued by the MDCO in connection with an audit or investigation under the Scheme, will entitle the MDCO to cease or suspend recognition of the Conformity Assessment Body under the Scheme.

6. Appeal against a Decision of the MDCO to Cease or Suspend Recognition or against an Instruction of the MDCO

Where a decision has been made by the MDCO to cease or suspend recognition of a CAB under the Scheme, or an instruction has been issued to a CAB by the MDCO in connection with any audits or investigations under the Scheme-

- ✧ the decision or instruction shall remain effective unless and until it is set aside in an appeal;
- ✧ an appeal against the decision or instruction lies to the CAB Recognition Appeal Board, but it must be lodged by the CAB in writing to the Board, c/o the Medical Device Control Office, within 4 weeks after the CAB is notified of the decision or instruction; and
- ✧ the Board's ruling in the appeal shall be final.

7. Enquiries

Enquiries concerning this booklet and the MDACS should be directed to:

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Department of Health,
~~18/F, Wu Chung House Rm~~ 3101, 31/F, Hopewell Centre,
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