

**Regulation of The Healthcare Accreditation Institute**  
**Concerning**  
**The Criteria and Method for Assessing Quality Improvement and Granting Accreditation Award**  
**BE 2563 (2020 AD)**

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As it is deemed appropriate to amend the criteria and method for assessing quality improvement and granting accreditation award to make them consistent with the policy concerning quality improvement and to enhance the effectiveness of the accreditation;

By virtue of Section 18 (5) (L) of The Royal Decree on the Establishment of The Healthcare Accreditation Institute (Public Organization) BE 2552 (2009) and as amended by The Royal Decree on the Establishment of The Healthcare Accreditation Institute (Public Organization) (2<sup>nd</sup> Edition) BE 2562 (2019), and the resolution of HAI Board in its meeting No. 5/2020 on 22 May 2020, a relevant regulation is issued as follows.

Article 1: This Regulation shall be called “ Regulation of The Healthcare Accreditation Institute Concerning the Criteria and Method for Assessing Quality Improvement and Granting Accreditation Award, BE 2563 (2020).”

Article 2: This Regulation shall come into force on the day after the date of its announcement.

Article 3: The following regulations shall be canceled:

- (1) Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2562 (2019);
- (2) Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Appeal against the Assessment Results and the Revocation of Accreditation, BE 2556 (2013).

For all any other regulations, notifications and orders concerning any matters already provided in this Regulation, that are in contrary or conflicting with this Regulation; the provisions in this Regulation shall be applied instead.

Article4: In this Regulation

“healthcare organization” means healthcare organizations, in accordance with the law on healthcare organization, which provide in-patient services. It shall also include healthcare organizations established by state agencies

“accreditation” means to certify that a healthcare organization has requisite operation and quality improvement processes which support good – quality health services and meet the standards stipulated by the Board. Such accreditation is an accreditation of work systems of a healthcare organization, not the assurance of clinical outcomes of individual patients.

“Institute” means The Healthcare Accreditation Institute (Public Organization).

“Board” means The Board of The Healthcare Accreditation Institute.

“Board Member” means a member of the Board of Healthcare Accreditation Institute.

“The Subcommittee” means The Advisory Subcommittee for Healthcare Accreditation

“Director” means The Director of The Institute.

Article 5: The Director shall have charge and control on the execution of this Regulation; and shall have the power to issue a notification, order or criterion, and/or any standard procedures beneficial to the compliance with this Regulation.

In case there is a dispute regarding the compliance with this Regulation, The Board shall have the power to arbitrate the dispute; and the arbitration of The Board shall be regarded as final.

## **Part 1**

### **General Provision**

Article 6: The goal of healthcare accreditation is to promote quality improvement of healthcare organizations on a continual basis by using self assessment against the standards set by The Board, together with a survey visit from the healthcare Accreditation Institute , as the tools for enhancing quality improvement.

Article 7: Healthcare organizations eligible for the accreditation award from the Institute include:

- (1) Healthcare organizations established by a government agency;
- (2) For private hospitals, the Institute will consider granting an accreditation award for each license of the establishment of the hospital;.
- (3) A network of healthcare organizations requesting for accreditation of Healthcare Network standards;
- (4) Healthcare organizations of any other kinds as necessary to meet the objective of the Institute, apart from those mentioned in (1) – (3), as seen appropriate by the Director.

Article 8: There shall be a subcommittee, or several subcommittees, to take the following duties:

- (1) Give suggestions or recommendations to the Director for the consideration to grant or to deny the accreditation award;
- (2) Analyze the survey report on quality process of healthcare organizations, in order to provide advice to the Director;
- (3) Take action on behalf of the Board in visiting a healthcare organizations to collect additional data, so as to support the advice mentioned above;
- (4) Any other duties as assigned by the Board.

Article 9: The assessment of quality improvement and granting accreditation award is divided into:

- (1) The assessment of quality improvement and granting accreditation award for the entire organization against the standards set by the Board;
- (2) The assessment of quality improvement and granting accreditation award against the program/disease specific standards set by the Board;
- (3) The assessment of quality improvement and granting accreditation award for healthcare organizations that develop a networking system in accordance with the standards set by the Board;

Article 10: Any healthcare organizations mentioned in Article 7 shall submit a letter to the Institute specifying the type or the category of the accreditation award they intend to obtain.

Article 11: The Director shall prescribe documents that healthcare organizations have to prepare for survey process.

## **Part 2**

### **The Survey Process and Accreditation Criteria**

Article 12: The assessment of quality improvement and granting accreditation award to healthcare organizations is divided into 4 levels.

- (1) level 1: Healthcare organizations organize an activity for reviewing kind of various events to facilitate the learning from occurring problems, leading to a more efficient solution.
- (2) level 2: Healthcare organizations create quality assuring system at the level of work units and work systems; and start using the standards as the basis for improvement.

- (3) level 3: Healthcare organizations emphasize driving quality improvement tasks throughout the entire organization, leading to performance results that meet the standards set by the Board; initiate integration and continuous learning, which are developed furthered from level 2 by completing a self-assessment form and accepting a survey visit in accordance with the process of the Institute.
- (4) Advanced level: Healthcare organizations further conduct quality improvement from level 3 by driving the improvement continuously and systematically; utilize outcomes to upgrade the healthcare organizations toward their vision and excellence by completing an assessment form and accepting a survey visit in accordance with the process of the Institute.

Article 13: The Director shall set up the criteria for the consideration and approval of:

- (1) An accreditation award for the entire organization in level 1 and level 2.
- (2) An accreditation award for specific diseases/system in accordance with the standards set by the Board

Article 14: The director, based on the suggestions or comments from the Subcommittee, shall have the power to consider and approve the granting of an accreditation for the entire organization in level 3 and Advanced Step by using the following criteria.

- (1) level 3: Healthcare organizations that would be qualified for the accreditation must have the scores from a survey visit for each chapter of the standard Part I-IV, not less than 2.50 from the full score of 5.00; and have been able to pass Essential safety standards as defined by the Board.
- (2) Advanced level: Healthcare organization that would be qualified for the accreditation must have the scores from a survey visit for each chapter of the standard, Part I-III, not less than 3.00, except for Part II-8 and II-9 that the scores of which must not less than 2.50, and the average score for Part IV must greater than 3.00; and have been able to pass Essential Safety Standards as defined by the Board. The total of all scores shall not less than 3.00.

For healthcare organizations applying for Advanced HA but their average scores are less than 3.00 but not less than 2.50, and the Subcommittee reach an agreement that such organization should be accredited for level 3; the Director shall have the power to consider approving this.

Article 15: In case that the Institute receives information from the surveyors that a healthcare organization applying accreditation for level 3 needs to conduct additional improvement for some items of the standards necessary for safety, or that its scores for some parts of the standards are less than 2.50, and the surveyors have assessed that such organization would be able to improve adequately within a period not exceeding three months; The Director may order to organize a focused survey for some specific issues within a timeline defined by the surveyors but not longer than three months from the time of the previous visit.

In case that such organization is not ready for the focused survey within the defined timeline, it should be regarded that the survey for level 3 has ended; and the Institute may consider granting the accreditation for level 1 or level 2 following the criteria set by the Director.

Article 16: The director, based on the suggestions or comments from the Subcommittee, shall have the power to consider and approve granting of an accreditation for healthcare organizations that have developed a networking system in accordance with the standards set by the Board. In doing so, it shall be in line with the criteria and method defined by the Board.

Article 17: The Director shall report to the Board in each monthly meeting the results of the accreditation in level 3, as well as the notions from the Subcommittee (if any).

For the accreditation in Advanced level and the accreditation in HA level, for which the opinions of the Subcommittee and that of the Director are in contrary; the Director shall submit the issue of such organization to the board for advice, and the Director shall have the power to consider approving the accreditation based on the advice and comments from the Board

Article 18: The Director shall define details and steps for the processes of any other surveys that do not aim directly for accreditation purpose.

Examples of other surveys mentioned in the first paragraph are preparation survey (preparing for accreditation in level 3), surveillance survey, a survey when there is a turnover of the highest executive person of the organization, a survey when there is a complaint against a healthcare organization, a survey when a healthcare organization is affected by a disaster, and the surveys in any other circumstances.

### **Part 3**

#### **Accreditation Certificate and logo**

Article 19: Accreditation certificate and accreditation logo can be used by only the accredited healthcare organizations; and such organizations shall not use the accreditation certificate and accreditation logo for any other facilities.

Article 20: Healthcare organizations can display accreditation certificate and accreditation logo only during the accredited period.

Article 21: The criteria for publicizing accreditation status of healthcare organizations shall conform to the criteria, methods and conditions set by the Director.

### **Part 4**

#### **Accreditation Period**

Article 22: Each type of healthcare accreditation shall have the accreditation period as follows:

- (1) Healthcare accreditation for the entire organization.
  - (1.1) The Accreditation for level 1 and level 2, the period is one year.
  - (1.2) The Accreditation for level 3, the period is three years.
  - (1.3) The Accreditation for advanced level, the period is three years.
- (2) For the accreditation for specific disease/system that have been improved in accordance with the standards set by the Board, and the accreditation for healthcare organizations that have developed a networking system in line with the standards set by the Board; the accreditation period is three years.

### **Part 5**

#### **Re-accreditation**

Article 23: Healthcare organizations shall submit a notification letter to the Institute requesting to get into the re-accreditation process for level 3 and Advanced level at least six months prior to the expiry date of accreditation.

In case that healthcare organizations fail to submit a notification letter to get into the re-accreditation process as mentioned in the first paragraph; the certificate of each respective type of the

accreditation shall be regarded as ended when it reaches the expiry date of such certificates. If those organizations intend to re-enter accreditation processes, they shall proceed with the step mentioned in Article 10.

Article 24: Healthcare organizations shall be regarded as having entered into the process of re-accreditation in level 3 or Advanced level, as mentioned in Article 23, after they submit self-assessment documents to the Institute and the Institute assesses that a survey visit for level 3 or Advanced level should be organized for such organizations

In case that healthcare organizations have entered into the process of re-accreditation as mentioned in the first paragraph already; but the process is not finished while the day reaches the expiry date , the status of such organizations shall be regarded as being temporarily accredited with a period of not exceeding three months, and when accreditation award is given, the date of new accreditation term shall be next to the previous expiry date. In this regard, the Institute must inform the board about this incident.

Article 25: Healthcare organizations that have received approval for re-accreditation for level 3 or Advanced level, the day of new re-accreditation team shall be counted next to the previous expiry date; and the length of such re-accreditation period shall conform to the length specified for each respective type of certification.

Article 26: Healthcare organizations will be regarded as having been entered into the process of re-accreditation for level 1, level 2, disease/system Specific Accreditation, and the Accreditation for Healthcare organizations Networking System , after they have submitted the required documents or have proceeded with any required tasks as defined by the Director.

Article 27: In case that the Institute confronts a disaster or any contingent event that affects the work process of the Institute in proceeding with the re-accreditation; the status of healthcare organizations that have entered into the re-accreditation process, as mentioned in Article 24, shall be in the state of being temporarily re-accredited until the normal work condition of the Institute can be resumed.

## **Part 6**

### **Expenses for Accreditation Processes**

Article 28: The expenses in applying for healthcare accreditation will incur in the step of a survey visit. The Institute will collect a survey fee from healthcare organizations based on the actual man-day used for each survey.

For the man-day mentioned in the first paragraph, the Institute will calculate by multiplying the total number of surveyors by the number of days spent for the survey.

Article 29: The survey fee covers the followings:

- (1) All the expenses incurred starting from the preparation of the Institute for organizing a survey, i.e. the expenses in reviewing the self-assessment form sent by healthcare organizations;
- (2) The expenses for the survey visits, which include the remuneration for surveyors, travel and accommodation expenses, as well as the expenses for reviewing survey results, notifying the results, and issuing the certificate of accreditation to healthcare organization;
- (3) The expenses in issuing accreditation certificate and accreditation logo, as well as any other related expenses, such as the expenses incurred in awarding ceremony.

The survey fee mentioned in the first paragraph does not cover the training that healthcare organizations want the Institute to organize for, as the preparation prior to receiving a survey visit; and does not cover the expenses for organizing a teleconference and web conference.

Article 30: In case that, after the survey visit, healthcare organizations may require another survey visit specifically for a certain issue, or that, after being accredited, there is a circumstance for which the Institute need

to conduct a special survey for healthcare organizations, such as the turnover of the highest executive person of the organization, and when there is a complaint against healthcare organizations; the Institute will collect a survey fee from healthcare organizations based on the actual man-day used for the survey.

Article 31: The Director shall announce the rate of survey fee, the rate of expenses for training, for organizing teleconference, web conference, and any other expenses related to the accreditation; and disseminate these rates generally to healthcare organizations. However, such rates of expenses shall not exceed the rates defined by the Board.

## **Part 7**

### **Required Action after Being Accredited**

Article 32: Healthcare organizations being accredited shall submit quality improvement plan for the period after receiving the awards; and shall report the progress of quality improvement to the Institute in line with the criteria and methods defined by the Director:

- (1) Healthcare organizations awarded with level 3 and Advanced level;
- (2) Healthcare organizations awarded with Disease/system specific Accreditation;
- (3) Healthcare organizations awarded with Network Accreditation

Article 33: Whenever there is an event affecting clients seriously and unexpectedly, or an incident affecting public confidence toward healthcare organizations, such organizations shall gather information and submit a written report to the Institute immediately or, as the latest, within thirty days after the day of such event, or the day. That there is an impact on public confidence towards healthcare organizations.

In case that healthcare organizations, fail to take action as provided in the first paragraph, the Director may send an inquiry letter to healthcare organizations about the execution of such action. Failure to report the incident mentioned in the first paragraph within a considerable period may be regarded as a reason for the Director to present such information to the team of surveyors for using as the basis for making a survey plan or compiling a survey report for such organizations, or present this information to the Subcommittee as the input data for consideration before giving advice or recommendation to the Director for considering further in granting approval for accreditation and in pursuing the denial of the accreditation.

Article 34: When there is a turnover of the owner of a healthcare organizations or the highest executive person of the organization, a merger of their business with other entities, or a major change in the type or the potential of their services; that healthcare organizations shall report in writing to the Institute within thirty days.

Article 35: In case that healthcare organizations face with a disaster or any contingent event significantly affecting their work process while holding the status of being accredited; the Institute shall organize a survey visit to assess the systems of such organizations to maintain safety in patient care process and to employ quality process in the operation of their works, free of charge.

## **Part 8**

### **Revocation of Accreditation**

Article 36: The accreditation of a healthcare organization will be considered to be revoked when the Institute has learned about an adverse event happened in the organization being accredited, which imposed an effect on the confidence in quality system, and the Institute has examined and collected relevant data and considered that such event imposed excessive impacts on the quality of services and safety of clients of such organizations, and that such event was resulted from the failure of the organization to maintain good quality of the process as defined in the standards adopted by the Institute. The Director shall present such information to the subcommittee and request for advice and recommendation within sixty days. In this regard, the Director shall

be the person who considers the order of the revocation of the accreditation and sends a letter to notify the healthcare organization about the revocation, describe the rights for sending an appeal, and the valid period allowable for the appeal.

Once the healthcare organization has reviewed the adverse event that affected the public confidence in the organization, analyzed it in a way leading to the improvement of work process to be more solid, and reported to the Institute accordingly; the Institute shall keep these data for organizing a follow-up and surveillance survey, as well as the survey for re-accreditation purpose.

## **Part 9**

### **Sending an Appeal**

Article 37: In case that a healthcare organization cannot pass the consideration for accreditation or their accreditation award have been revoked, this organization can exercise their rights to send an appeal to the Director within fifteen days after the day of getting notified about such order. In the appeal letter, the healthcare organization shall enclose additional data or evidences against the reasons for not passing the consideration or for the revocation of accreditation.

The Director shall consider the appeal request. In doing so, a taskforce can be appointed to scrutinize the appeal and make relevant recommendations.

In case that the Director agrees with the appeal, he/she shall proceed to change the order accordingly based on his/her opinion and notify that healthcare organization about the appeal result within thirty days after the day of receiving the appeal request.

In case that the Director disagrees with the appeal, either totally as a whole or in some parts, he/she shall quickly report his/her opinions along with supportive reasons to the Board for consideration within thirty days after the day of receiving the appeal request.

The Board shall consider the appeal request completely within thirty days after receiving the report from the Director. The result of the consideration by the Board shall be regarded as final. The Director shall then proceed accordingly following the resolutions of the Board

In a case of necessity resulting that the consideration cannot be finished within the mentioned period, the Board shall notify the healthcare organization in writing prior to the end of such period. In this circumstance, the consideration period can be extended further but not exceeding thirty days from the end of the previous period.

## **Part 10**

### **Survey Data and Status of Accreditation**

Article 38: Healthcare organizations shall send reliable data to the Institute and surveyors . In case that healthcare organizations intend to provide falsified data or cover some important data, but the surveyors know about this during the survey; the surveyors will discontinue the survey activities immediately. Or if the institute recognizes this after the healthcare organizations have been awarded with the accreditation, it may lead to the revocation of the accreditation of such organization.

Article 39: Documents and data sent to the Institute or surveyors for a review prior to an actual survey visit, as well as any other data received additionally during the survey visits, will be kept confidential. Disclosing any data furnished with the names of healthcare organizations, or any data that can be guessed as belonging to a specific organization, to any outside persons or agencies, cannot be done without a prior written consent from such organization

Article 40: For the benefits of public and for making a public relation about healthcare organizations that have been awarded with accreditation, the Institute can publicize the status of the accreditation and the history of the accreditation of each organization through the website and any other media that the Institute has created.

Article 41: The Institute can use the survey data obtained from healthcare organizations in a research, the result of which can be useful for analyzing the national situation of healthcare service, and for formulating an appropriate health policy. However, the findings of the research disclosed to the public shall be the overall data as a whole, not revealing the name of organization

## **Part 11**

### **Transitional Provisions**

Article 42: Accreditation certificate and logo issued under the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2556 (2013) and the amendment afterward, and those issued under the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2562 (2019), shall be regarded as the accreditation certificate and logo issued under this Regulation. The certificate and logo issued under the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2562 (2019) shall be valid until the expiry date of accreditation certificate and logo as provided in the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2556 (2013) and the amendment afterward, and as provided in the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2562 (2019).

Article 43: The renewal of accreditation certificate and accreditation logo executed under the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2556 (2013) and the amendment afterward, and those executed under the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2562 (2019) shall be regarded as the execution under this Regulation.

Article 44: Any processes concerning the accreditation carried out under the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2556 (2013) and the amendment afterward, and those carried out under the Regulation of The Healthcare Accreditation Institute (Public Organization) Concerning the Criteria and Method for Healthcare Accreditation, BE 2562 (2019), which have not been completed yet on the effective date of this Regulation, shall be continued in accordance with the regulations previously enforced until they are completed, or until they can be carried out under this Regulation.

Announced on: the 1<sup>st</sup> of June 2019

(Mr. Theerapol Topanthanont)  
Chairperson of HAI Board