

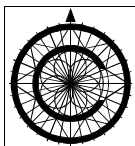
Certification of TB DOTS Centers and Providers Systems Design

Submitted by:
Jose Acuin, MD, MSc

07 March 2003



USAID/Philippines



Chemonics International Inc.
Contract No. 492-C-00-02-00031

This study received support from the Office of Population, Health and Nutrition (OPHN), Philippine Mission, United States Agency for International Development, under the terms of Contract No. 492-C-00-02-00031. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

For more information, please contact:
Philippine TIPS, Unit 1608 West Tower, Philippine Stock Exchange Centre, Exchange Road,
Ortigas Center, Pasig City 1605, Philippines.
Tel: +632 687-7135
Fax: +632 687-2195
E-mail: phil_tips@philtips.com

Table of contents

Goals of certification.....	5
General eligibility requirements for certification.....	5
Purpose of certification survey.....	5
Scope of certification survey.....	5
Outcomes of certification survey.....	6
Certification awards.....	7
Length of certification award.....	7
Information accuracy and truthfulness.....	7
Transparency and accountability.....	7
How to apply for certification.....	7
Planning the certification visit.....	8
Self-assessment.....	9
Conduct of on-site certification survey.....	10
The role of the PhilCAT Certification Committee.....	10
General role of the PhilCAT Certification Coordinator.....	11
The survey team.....	12
The certification decision process.....	13
Appeals of decision not to certify.....	14
Cost of certification survey.....	14
Confidentiality.....	15
Maintenance of certification.....	15
Re-certification based on the PhilHealth BenchBook standards.....	15
Public disclosure of certification status of TB DOTS Centers.....	16
Certification award display and use.....	17
Reporting requirements in between certification surveys.....	17
Monitoring in between certification surveys.....	17
The TB DOTS Center Certification Standards.....	19
General infrastructure.....	19
Equipment and supplies.....	20
Management and information systems.....	21
Human resources.....	22
Certification of DOTS professional providers.....	24
Goals of certification.....	24
General eligibility requirements for certification.....	24
Purpose of certification survey.....	24
Scope of certification.....	25
Outcomes of certification process.....	25
Certification awards.....	25
Length of certification award.....	25
Information accuracy and truthfulness.....	26
Transparency and accountability.....	26
How to apply for certification.....	26

The certification decision process	26
Appeals of decision not to certify	27
Cost of certification	27
Confidentiality.....	27
Maintenance of certification.....	27
Re-certification based on the PhilHealth BenchBook standards.....	27
Public disclosure of certification status of TB DOTS Centers.....	28
The TB-DOTS professional provider standards for initial certification	29

Goals of certification

Certification is a process that assures the general public and payers of health care that a TB-DOTS Center is capable of providing safe and effective DOTS services to TB patients. Despite evidence of its effectiveness in treating TB, DOTS is a relatively new intervention that has not been fully institutionalized and integrated into the health care system. Certification aims to standardize the provision of DOTS by imposing a uniform set of standards and criteria governing the human, material and administrative resources of a TB DOTS Center. Compliance with these standards and criteria is an excellent starting point on which the accreditation process of PHIC can begin.

General eligibility requirements for certification

To be eligible for a certification survey, a health care center must meet the following requirements

- The TB DOTS Center must be currently operating as a health care facility.
- The TB DOTS Center must be willing to provide DOTS service to TB patients.
- The TB DOTS Center must be willing to assume responsibility and be held accountable for its operations.

Purpose of certification survey

- *Proof of capability*

The certification survey is a process that determines the degree to which a TB-DOTS Center complies with the minimal basic requirements for the safe and effective provision of DOTS services to TB patients. These requirements are structural in nature and are contained in the core standards for certification. Although they are not meant to limit centers from adding or improving resources that it considers appropriate to the health needs of its clients, compliance with them does provide solid proof that centers are capable of further improvement of the quality of its services.

- *Demonstration of ongoing performance improvement*

For centers to maintain certification, PhilCAT and PHIC will expect them to demonstrate compliance with the standards of the *Philippine Health Insurance Corporation BenchBook of Performance Improvement (PhilHealth BenchBook)* as appropriately adapted for TB-DOTS Centers. These standards expect previously certified centers to integrate process and outcomes documentation, evaluation and action to improve care in its routine operations.

Scope of certification survey

The certification survey is divided into two phases each with its own general scope.

- ***Initial certification survey***

The survey scope includes all of the structural standards required by PhilCAT and PHIC. All standards will be applied uniformly to all applicant centers and compliance with the core standards will determine whether or not certification is awarded. The survey team may consider specific institutional, cultural or legal factors that can influence compliance to these standards and consequently shape its decision. Such modifications do not prejudice future expectations that all TB-DOTS Centers will provide a uniform set of processes and procedures in providing DOTS services. The survey team may thus recommend additional or alternative proof that the initial certification standards are met or will be met at a pre-defined reasonable period of time.

- ***Re-certification survey***

The survey scope includes the structural standards for initial certification PLUS all of the seven standards of the *PhilHealth BenchBook* that have been adapted for TB-DOTS Centers. Compliance with these standards is a three phase process that sequentially involves the following:

1. Documentation of processes and outcomes of care
2. Evaluation and analysis of processes and outcomes of care to identify areas for improvement
3. Taking action to address the identified areas of improvement

The seven standards are the following

1. Patient care
2. Safe practice and the environment
3. Leadership and management
4. Human resources management
5. Information resources management
6. Patients' rights and organizational ethics
7. Performance improvement

In the re-certification survey PhilCAT and PHIC will prioritize and expect demonstration of compliance to the first two standards which are deemed critical to safe and effective DOTS service provision. However, since the last five standards are considered necessary administrative ingredients to the achievement of the first two standards, centers should also show evidence that there are organizational resources and mechanisms conducive to effective patient care, safe practice and environment protection.

Outcomes of certification survey

The Certification Committee of PhilCAT makes certification decisions based on the results of the certification survey. A applicant health care facility can receive one of the following certification decisions:

- ***Certified***

A certification decision that results when a health facility demonstrates acceptable compliance with the core standards for initial certification and / or re-certification.

- ***Not certified***

A certification decision that results when an applicant health care facility consistently fails to demonstrate compliance with the core standards for initial and / or re-certification, when PhilCAT withdraws the certification for other reasons or when the health center voluntarily withdraws from the certification process.

Certification awards

Certified TB-DOTS Centers receive both the results of the certification survey and the PhilCAT certificate.

Length of certification award

Certification awards have a one year effectivity.

Information accuracy and truthfulness

The health care facility must at all times provide accurate and truthful information in the certification process. If facility falsifies information relevant to its application for certification, either by commission or by omission, the certification will be immediately terminated or for applicants for initial certification, the facility will be ineligible for re-evaluation for at least one year. Falsification of information involves modifying, adding or deleting information for the purpose of misrepresentation.

Transparency and accountability

PhilCAT shall conduct the certification process with pre-defined decision making rules and administrative procedures. Deliberation proceedings will be fully documented and stakeholders can expect that the entire process shall be fully open for scrutiny whenever this is required. PhilCAT is accountable to PHIC for the quality of its certification process and will provide the latter with regular updates of its certification activities as well as additional information if so requested.

How to apply for certification

Any health care facility that fulfills the general eligibility criteria for certification may fill up and submit an application for certification available at the PhilCAT or PHIC office or website. The application form requires applicant (facilities) to provide PhilCAT with essential information including the following:

- The name, address and ownership of the facility
- Identities and qualifications of the management and staff of the facility
- The number and types of medical devices owned by the facility
- Available drugs in stock
- Services provided by the facility
- Volume and types of cases serviced by the facility

PhilCAT will also require submissions of proof that the facility has complied with all the standard legal and statutory requirements relevant to the facility's operation. This will include licenses and permits issued by local government agencies.

The center may apply in either electronic or paper format to:

Philippine Coalition Against Tuberculosis (PhilCAT)

Secretariat: Quezon Institute Compound E. Rodriguez Avenue, Quezon City

Telefax (632) 7498990

Email address: philcat@pacific.net.ph

Planning the certification visit

Upon receipt of the completed application form and attachments, PhilCAT will review the documents for completeness and will contact the organization to assist it in preparing for the certification visit (usually within 30 days after submission of application). PhilCAT will exert all efforts to shorten the turnaround time. Applicant facilities must ensure the completeness of the documents in order to avoid returned submissions.

- ***Assignment of PhilCAT Certification coordinator***

PhilCAT will assign each applicant facility a certification coordinator that will be personally responsible for advising the facility in its preparation for the survey, for answering and clarifying questions and other issues related to the survey and for coordinating the different participants and logistical requirements of the survey process itself. (Is the coordinator's signature mandatory before sending on to PhilCAT?)

- ***Role of the PhilCAT coordinator in self-assessment***

The PhilCAT coordinator will assist the facility in conducting the pre-survey self-assessment, will guide the facility in the interpretation of the certification standards and in the use of the self-assessment tool, and will advise the facility on the appropriate courses of action to take based on the results of the self-assessment. The courses of action may include pursuing the application process as planned, deferring further pursuit of the application pending satisfactory address of the results of the self-assessment, or withdrawing from the certification process completely.

Disagreements between the center and the PhilCAT coordinator on what courses of action to take will be elevated to the Certification Committee for resolution and the Committee decision will be deemed final.

- ***Certification Committee action on self-assessment results***

If, based on the results of pre-survey self-assessment, a decision to pursue the certification application is reached, the facility will forward the results of the self-assessment, endorsed by the PhilCAT coordinator, to the Certification Committee to request for the certification survey.

The Certification Committee will review the results of the self-assessment and will schedule the date of the certification survey.

- ***Role of the PhilCAT coordinator in preparing the survey plan***

The PhilCAT coordinator will then work with the facility to prepare a survey plan depending on the size and complexity of operations of the facility. The survey plan specifies the following aspects:

1. Actual date, time and duration of the survey visit
2. Sequence of activities and persons involved in each activity
3. Documents and other materials that are required for the survey

The survey schedule should be announced ahead of time to allow the facility to prepare itself and for its personnel to schedule their availability. Remember: the goal is quality improvement, not to catch TB DOTS Center personnel unawares. (The caveat to this is that the facility may, out of genuine Filipino hospitality, prepare to receive the visitors with food and tokens, thus inadvertently exerting pressure on the survey team, which may then find it difficult to point out deficiencies. The facilitative role is best left to the coordinator, while the survey team can be as businesslike as necessary.) The TB DOTS Center will be informed that the certification fees include meals and that it is preferred that they do not serve anything as a matter of procedure.

Requests for changes to the survey visit must be made in writing and made known to all parties concerned at least two weeks before the survey date. If the facility fails to inform PhilCAT of changes in the date of the survey at least two weeks in advance, it will forfeit all or part of the survey deposit.

Self-assessment

Applicant facilities will be given every opportunity to demonstrate compliance to the certification standards. This is why the pre-survey self-assessment is an integral part of the certification process. Self-assessment accomplishes the following objectives:

- It enables facilities to pre-determine its areas of strengths and weaknesses. This is in itself an invaluable learning opportunity that enables the organization to systematically perform a comprehensive and critical examination of the important aspects of its service.
- It enables facilities to institute corrective action on its deficiencies and thus improve its performance. Continuing quality improvement is essential to every organization whether or not it seeks certification or accreditation.
- It improves the chances for being awarded certification so that the survey visit becomes an opportunity for the facility to “show off” its achievements and for PhilCAT to validate what has already been noted in the self-assessment report.

Conduct of on-site certification survey

At the mutually agreed upon date and time, a team of three highly skilled and experienced surveyors will be sent by PhilCAT to the center to conduct the certification survey.

The general program of the survey process will be divided into the following components:

1. General introduction to the facility
2. Interviews of key personnel and patients
3. Document review
4. Actual observation of key facility processes
5. Team meeting to integrate findings
6. Concluding conference

The team should have some time for themselves (30-60 minutes) to piece together the separate observations they made.

During the survey, any of the facility personnel and patients may be interviewed. Facility personnel must fully cooperate with the surveyors and provide factual information to the best of their abilities. Surveyors may request for any document pertaining to (center) operations; preparing all facility documents ahead of time will therefore greatly conserve time and effort. It is important that the facility carry on its usual activities as much as possible and NOT totally suspend its operations in order to entertain surveyors. The PhilCAT team will ensure that the survey process will create only as much disruption as necessary to conduct a fair and reliable assessment of the facility's performance

In the concluding conference, the PhilCAT survey team provides feedback on the facility's performance and shares its general findings with its personnel. Because the survey process is essentially a sampling study, the personnel must be prepared to offer additional evidence of compliance to the certification standards whenever they feel that this is necessary. The survey team must take precaution NOT to give the impression that the certification decision has already been made. Rather the concluding conference must be perceived by everybody as a final chance to validate the degree of compliance to the standards and an occasion to give feedback on major or minor deficiencies and how they should be remedied. The facility administrator shall signify his concurrence with the survey findings by signing the accomplished survey form.

The role of the PhilCAT Certification Committee

A national reference center which interprets and oversees the implementation of the certification process through a uniform application of the certification standards using valid and replicable survey methods is critical to the effectiveness and credibility of the PhilCAT TB DOTS Center certification program. The PhilCAT certification Committee will fulfill this role.

There are three principal functions of the PhilCAT Certification Committee:

- *Administrator*

The Committee develops, promulgates and evaluates the effectiveness of the policies and procedures governing the entire certification process. It manages the following activities:

- 1.1 review of application documents
- 1.2 assignment of certification coordinators to specific TB DOTS Centers
- 1.3 identification and mobilization of survey team members (could be a task for secretariat)
- 1.4 coordination of the survey activities (secretariat?)
- 1.5 review of survey results
- 1.6 coordination of in-between survey monitoring activities
- 1.7 review of in-between survey results
- 1.8 regular review of the national database of all documents generated by the certification process (secretariat; regular review of database may be more appropriate)
- 1.9 publication and dissemination of the results of certification surveys (secretariat task, but regular dissemination of lists of centers should be approved by committee)
- 1.10 awarding of certification seals

- *Adjudicator*

The Committee is the final interpreter and promulgator of the certification standards and discharges the following functions:

- 1.11 receives self-assessment results and decides on the fitness of the health care facilities for certification survey
- 1.12 deliberates on survey results and decides on the outcome of certification surveys
- 1.13 decides on questions arising from the appropriate interpretation and application of the certification standards during surveys
- 1.14 decides on questions related to the acceptability of evidence of compliance to the different standards proffered by applicant health care facilities
- 1.15 deliberates and decides on the merits of additional evidence proffered by applicant facility during appeals of decisions not to certify
- 1.16 deliberates and decides on the acceptability of additional evidence that may be required by surveyors to address specific deficits
- 1.17 deliberates and decides on the merits of reports and other information generated by the in-between survey monitoring program

- *Training design*

The Committee plans and promulgates policies and procedures governing the training of surveyors, certification coordinators, TB DOTS Centers and TB DOTS providers.

General role of the PhilCAT Certification Coordinator

It is important to keep in mind that the goal of certification is to improve the quality of DOTS provision through a collaborative engagement of the provider by DOH, PhilCAT, PHIC and other stakeholders. The Certification Committee may appoint the provincial or

city NTP coordinator may very likely play this role although other PHIC, DOH or PhilCAT personnel may be tapped for this purpose. In this respect the PhilCAT Certification Coordinator represents the physical interface between TB DOTS Center and PhilCAT. The Coordinator brings to the TB DOTS Center a set of knowledge and skills on how best to implement a culture of continuous quality improvement. The triggers he uses to introduce these concepts and skills to the TB DOTS Center are the deficiencies that the TB DOTS Center itself identifies in the process of self-assessment. What can be more natural than for the certification coordinator, once he spots deficiencies, to immediately point out to the Center how these can be remedied? The PhilCAT Certification Coordinator should not be seen as an inspector / inquisitor but as a PARTNER; complying with his advice will not guarantee certification but should be seen as an advice in improving performance. This may not be apparent in the initial certification process but in the re-certification where the focus is quality improvement, the goal of certification is NOT certification itself. The end is improving performance. The fact that certification is just a tool should never be lost on all concerned. And that as a tool it can be used wrongly or rightly.

The PhilCAT certification coordinator is a training specialist and should NOT be a member of the survey team. This quickly eliminates conflict of interest. If PhilCAT can identify independent training organizations, then it can partner with these organizations to provide technical support to TB DOTS centers. The NTP coordinator can probably be assigned this role for the initial certification application and self-assessment processes. The NTP Coordinator might not be able to provide technical support in the re-certification processes unless he is trained to train others in quality improvement / management.

The survey team

There should be at least two, ideally three members to relieve any decision-making impasse and to guarantee that it will take more than just one member to make a major decision. The regional NTP coordinator, local PhilCAT personnel and other leading members of the local community may be called upon to be members of the survey team.

The three experts are chosen on the basis of expertise, not on the stakes they hold. (The stakeholders may be represented in the National Certification Committee.) The following should be the fields of expertise to be covered by the survey team members:

1. clinical patient care
2. health care management and administration
3. technology management and safety - these cover drug / laboratory device management / infectious control and waste disposal issues

The members of the survey team shall be trained to apply ALL of the standards although, if all three members are present, they may focus on their area of expertise. The reason for this is so that the team members can check and balance each other's views and so that any member may take upon himself the tasks of the other team members if necessary.

There will be no overlapping of standards to be rated by each team member. During the team meeting, the members present to the rest of the team the scores that they gave to the standards assigned to them. A general discussion follows on the validity of the scores given. The purpose of the meeting is to integrate all the information collected by the different team members into the scores for all the standards.

In this way, there are three levels in certification: a facilitative, self-assessment level, a survey which records the state of health service delivery and the adjudicative/decision-making role of the national certification committee.

The certification decision process

Certification decisions are made by the PhilCAT Certification Committee based on the findings of the survey team. The certification decision is either (a) certified or (b) not certified. All unresolved issues, deficiencies and all additional requirements must be addressed by the center before a certification decision is made. For example, the survey team may require additional evidence of adequacy of drug supply and a follow-up focused visit may have to be made to determine this. Another example would be a facility offering an alternative mechanism or resource in order to comply with a core standard such as laboratory microscopy. The facility must satisfy all these conditions within a time frame and through procedures (e.g., document submission, additional follow-up visit) as determined by the PhilCAT Certification Committee before it receives a certification award.

A deficiency may be considered minor or major. A major deficiency is a failure in safety or effectiveness that the facility cannot remedy within a time interval that constitutes a sizeable proportion of the certification duration, say 6 months if the certification duration is one year. A center may be certified after it has provided documentary evidence of remedial action on minor deficiencies without a follow-up survey needed.

The certification decision will be based on an algorithm that considers minimal passing scores on the certification standards. Each standard is scored “fully met”, “partially met” or “not met”. Depending on whether the standards are in the core list or not, the individual standard scores are then weighted and the resulting products are aggregated (in a standard manner). Consideration of both the individual weighted standard scores and the aggregate score will indicate whether the center has met the minimum expected compliance with the certification standards.

The Certification Committee will act purely on the detailed report of the Survey Team unless it has serious reasons for verifying the findings for itself. The Committee is a central / national committee and does not have to be near the facility. Of course it needs to oversee the survey team but its main function vis a vis the team is to relieve the team of any pressure from the facility to fudge its findings because the certification decision rests squarely upon the Certification Committee, not the team.

As the sole arbiter in the interpretation of the standards, criteria and indicators, the Committee members should be immediately accessible to members of the survey team

should any questions about interpretation arise in the field so that a clear decision as to whether or not the survey findings constitute clear evidence of compliance to any standard can be quickly made. These are critical ministerial functions that PhilCAT must fully take upon itself if it is serious in discharging the deputizing mandate given to it by PHIC.

Appeals of decision not to certify

Upon receipt of the decision not to certify, the center has two weeks to notify the PhilCAT Board in writing of its intention to appeal the decision. The center has an additional four weeks to submit additional appropriate information and new data to justify its appeal. The PhilCAT Board will only act on the appeal and consider amending the decision upon receipt of this fresh information; otherwise, it shall consider the decision as acceptable to all parties concerned. The Board considers the appeal and the supporting information in making a final determination of the certification status. The Board will take not more than 4 weeks from receipt of all documents supporting the appeal to provide an official decision. This implies that the decision not to certify should be detailed enough to give the applicant health facility the opportunity to rectify.

Cost of certification survey

The center shall pay a non refundable basic application and survey fee of five thousand pesos (PhP5000). The survey fee covers the following:

- Surveyors' honoraria for preparing for and conducting the survey
- Surveyors' honoraria for preparing the survey report and for other post-survey activities
- Administrative costs to PhilCAT for operating the certification program

Surveyors' per diem which includes travel costs, accommodations, meals and incidental expenses is not included in the 5,000 pesos survey fee.

The surveyors' per diem have to be standardized based on the following parameters:

1. the length of the actual survey time and pre- and post-survey activities as measured by the complexity and size of the facility
2. the travelling time to the facility as partly measured by the distance of the facility from a reference point (for example, the PHIC office). Baseline costs can be set for travel within the municipality where the facility is located. Standard costs can be added for travel outside of the municipality.

Per diems should cover food and transportation only and not salary or opportunity cost replacement. The actual effort to conduct the survey should be seen as **RECOMPENSED BY TRAINING FROM PHILCAT AND HANDS ON EXPERIENCE** which the surveyors can then profit from in many ways. The employers of these surveyors should also perceive their time spent in surveying as quality improvement training which they can then bring back to their organization.

Half of the survey fee (2,500 pesos) must be paid to PhilCAT when the survey date has been fixed. The balance of the fee (2,500 pesos) shall be paid upon receipt of PhilCAT's invoice statement for the provision of services. The survey report will only be released upon full payment of the certification fees. PhilCAT may request for access to funds from other sources to cover for additional costs to be incurred in surveying facilities that require substantial travel expense.

Confidentiality

PhilCAT shall not publicly release any finding generated by the certification process or any information about the center collected during the survey visit. The only information that PhilCAT will publicly release is the center's certification status, that is, whether or not the center is certified and, possibly, the aggregate score. The center may, upon its own discretion, release additional information regarding the findings of the certification survey team.

Maintenance of certification

A certification award is valid for one year but renewable every year for three years unless revoked by PhilCAT or voluntarily surrendered by a certified center. PhilCAT will not automatically renew the certification status after three years. Rather the center must again apply and undergo a full re-certification survey, satisfy all additional conditions that may be required of it and provide sufficient evidence of compliance with all PhilCAT standards.

Re-certification based on the *PhilHealth BenchBook* standards

Effective DOTS service provision is essentially based on special attention to the processes of following-up patients in active treatment to ensure compliance and good clinical outcomes. Compliance with the initial structure-based certification standards do not necessarily ensure that the goals of DOTS will be achieved. Initially certified TB-DOTS Centers must therefore move quickly from the paradigm of proving capability to the paradigm of proving quality. Compliance with the seven clusters of standards that PHIC uses for accrediting health care organizations, after appropriate adaptation, will bring TB-DOTS Centers within the new quality framework of PHIC. Quality consists of doing the right things the right way. To be re-certified, centers must demonstrate that they are documenting, evaluating and taking action to improve their processes of patient care and clinic management.

The standards are deliberately kept open and non-prescriptive to encourage creativity, innovation and flexibility. Quality improvement is not about having a defined number of drugs in the shelves. It is about the facility assuring itself and its patients that it will meet their drug supply needs every time and that the facility has ways on informing itself if the drug supply can not do this in advance. (This paragraph may undermine the idea of certification based on standards of evidence-based medicine.) Not so. The facility informs itself through TB prevalence estimates of how much drugs it should stock. This IS evidence based medicine. Contrast this with being dictated on how much drugs to stock without any reference to actual or potential utilization.

- ***Re-certification processes***

The processes for re-certification and initial certification are very similar to each other. Reference to the corresponding sections regarding the initial certification should be made. Two months before the end of the certification period, PhilCAT will send a Request for Re-certification Form to the Center. The center is responsible for completing the form and sending it back to the PhilCAT office.

A new self-assessment packet is then sent to the Center, consisting of the initial structure-based certification standards and the PhilHealth BenchBook-based re-certification standards. As before, a Certification Coordinator will be sent by PhilCAT to assist the Center in preparing for the re-certification survey and in conducting, evaluating and acting upon the results of the self-assessment. (If an NTP coordinator was used for the initial certification, the same person if not oriented to the Benchbook, may not be the person to send. PhilCAT may have to think about retraining all its coordinators before year two of certification.) I agree.

Once the Center has been adequately prepared, the survey date and time is mutually agreed upon by the PhilCAT survey team and the Center.

The Certification Coordinator, in close communication with all parties concerned, prepares a survey plan.

- ***Re-certification on-site survey***

The conduct of the re-certification survey is similar to the initial certification survey. This time, however, the Center is expected to demonstrate evidence of compliance to both initial certification and the adapted *PhilHealth BenchBook* standards. Each standard is again graded “met”, “partly met” or “not met”.

- ***Re-certification decision processes***

Using a new set of scoring, weights and aggregation rules, the decision to re-certify or not to re-certify is arrived at by the survey team and approved by the PhilCAT Certification Committee. Procedures for communicating and fulfilling conditions for re-certification and for appeals of decisions no to re-certify are the same as those for initial certification.

Public disclosure of certification status of TB DOTS Centers

PhilCAT is committed to making relevant and accurate information about surveyed TB-DOTS Centers available to the public. Such information is a powerful motivator for TB-DOTS Centers to continuously improve their services. Such information also educates the public about the role of certification in ensuring quality of services. Finally, health care consumers and payers stand to make better informed choices if the results of the initial certification and re-certification are made known to them.

However, in order to preserve the openness and trust between PhilCAT and the TB-DOTS Centers, details of the survey findings will NOT be released. Only the certification status as well as their aggregate scores for each cluster of standards will be publicly disclosed. Please refer to the section on Confidentiality for more details.

Certification award display and use

PhilCAT will provide a certified TB DOTS Center with an official award of certification at the time of initial certification and at the time of re-certification. The award is provided free of charge but remains a property of PhilCAT. The award will specify the period of certification for which it is valid. (Should also be suitable for prominent display; people could also be asked to look for the award as a symbol of quality care in DOTS; a unique year and month sticker could indicate validity of the award, much like a license plate)

OK

The PhilCAT certification award must be displayed prominently but only within the period during which the certification is valid. The TB DOTS Center may use the award only for the purpose of informing the public of its DOTS services and for other purposes that PhilCAT may additionally allow. The TB DOTS Center must not use the award to misrepresent its certification status or the facilities and services to which the certification award applies.

The award must be returned to PhilCAT

1. when the TB DOTS Center's certification status is denied or withdrawn for whatever reason
2. when the TB DOTS Center's name has been changed.

Reporting requirements in between certification surveys

Certification will not apply to the following changes in the TB DOTS Center, thus a report of such changes must be made to PhilCAT:

1. a change in ownership or management
2. a change in location or a significant change in the physical set-up
3. a change in certified personnel, ex. Trained medtech or NTP-accredited doctor who have moved out and have not been replaced by trained personnel?

The notification report must be submitted in writing to PhilCAT not more than 30 working days after the change has occurred. Failure to notify PhilCAT in time may result in withdrawal of certification.

A re-certification survey or a focused survey may be made following the changes enumerated above. PhilCAT must also have a system of reporting these changes to PHIC to limit inappropriate claims.

Monitoring in between certification surveys

Certification is premised on continuous fulfillment of the conditions for certification. A certified TB DOTS Center is thus expected to provide PhilCAT with proof that it continues to comply with the certification or re-certification standards. Such proof may consist of the following

1. evidence of improved compliance to standards that have been previously identified by a survey as unsatisfactorily addressed by the TB DOTS Center and thus have merited recommendations for further action
2. evidence of continuing compliance to standards that PhilCAT has deemed critical and worthy of continuous surveillance

3. evidence of compliance to new and urgent requirements that have been developed in between certification surveys

Such evidence may take the form of the following:

1. written reports of action taken and outcomes of such action to address specific issues of compliance
2. copies of TB DOTS Center documents to support that the recommendations made by the PhilCAT survey team have been addressed
3. focused follow-up surveys. The time and schedule of these in between certification surveys shall be announced to the TB DOTS Center as may be deemed appropriate by PhilCAT.

The outcomes of these monitoring activities may be any of the following:

1. The TB DOTS Center's certification is maintained
2. The TB DOTS Center's certification is maintained pending additional evidence of compliance with standards
3. The TB DOTS Center's certification is withdrawn prematurely by PhilCAT.

The TB DOTS Center Certification Standards

The general rubric of the conditions for certifications is as follows:

Goal

Standard

Criteria

Possible Indicators

Standard

Criteria

Possible Indicators

The goal declares the overall intent of the standards under it. This allows for a more holistic, broader and flexible approach to the standards and discourages a prescriptive interpretation. Both PhilCAT and the TB DOTS Centers should strive to be true to the intent and spirit of the standards by adhering to a uniform but appropriately adapted application.

The standards are statements of ideal performance.

The criteria under each standard provide specific and measurable indicators that will help determine whether or not the standard has been met.

General infrastructure

Goal: The TB DOTS Center provides a safe and effective physical environment to its staff and patients.

Standards:

1. Patients have safe and convenient access to and from the TB DOTS Center.

Criteria:

1.1 There is a large and clear sign outside the TB DOTS Center bearing its name.

1.2 Entrances and exits are clearly marked and free of obstruction and other hazardous conditions.

1.3 There are resources to inform patients of the daily and hourly schedule of clinic activities.

(Possible indicators: signages, leaflets and / or public lectures detailing clinic days and times)

1.4 There are resources to ensure the quality of patient waiting.

(Possible indicators: waiting area has space and seats that are adequate to usual patient load; well ventilated and illuminated waiting area)

(If clinic is multidisciplinary or an OPD, are the above specific to DOTS center-related activities only or are they true for the general clientele, or does it mean adding more chairs from the original setup to accommodate influx of DOTS patients; will there be segregation of patients, as OWWA requires for OFW clinics? Comment goes for all three standards.) These standards are applicable whether or not the TB DOTS Center is a stand alone. As indicated the goal is safe and convenient access to the TB DOTS Center . it does not prescribe segregation of patients. The number of chairs is

up to the TB DOTS Center to decide based on its observations of how many patients on the average need to stand up while waiting for example.

2. The TB DOTS Center provides facilities for the comfort and privacy of its patients and staff.

Criteria:

2.1 The TB DOTS Center maintains a generally clean and wholesome environment within and immediately outside its premises.

(Possible indicators: Rooms, corridors, toilets, office and clinic spaces, laboratories and pharmacy are clean and free of clutter; examination beds have clean linen, etc.)

2.2 There are resources to ensure adequate lighting.

(Possible indicators: Interiors have lighting adequate for clerical activities and physical examination.)

2.3 There are resources to maintain adequate and clean water for personal hygiene and sanitation purposes.

(Possible indicators: Covered water supply for handwashing and for cleaning / flushing toilets.)

2.4 There are resources to ensure the privacy of the staff-patient encounter.

(Possible indicators: Examination rooms are adequately concealed; adequate linen, etc)

3. The TB DOTS Center provides facilities for the safety of its patients, staff and facilities.

Criteria:

3.1 There are resources to maintain general cleanliness of the clinic and provide antiseptics of clinical and laboratory instruments and equipment.

(Possible indicators: Cleaning implements; disinfectants and soaking trays, etc.)

3.2 There are resources for safe and segregated disposal of biological and hazardous wastes and of general trash.

(Possible indicators: Garbage segregation scheme in place; ecologically safe and legally approved waste disposal system, etc.)

3.3 There are resources for secure storage of TB drugs.

(Possible indicators: Drug cabinets, pharmacies, have functional doors, locks, staff members clearly responsible for securing drug storage areas, etc.)

3.4 There are documented, disseminated and implemented procedures to identify and address the risks of contamination of the staff and patients from sources of infectious diseases.

(Possible indicators: prominently displayed guidelines for infection control, minimizing TB contagion, needle stick injuries, etc.)

Equipment and supplies

Goal: Clients receive adequate and effective diagnostic and therapeutic services at every phase of their management from screening for TB to rehabilitation.

Standards:

4. The TB DOTS Center clients have continuous access to accurate and reliable TB diagnostic tests.

Criteria:

- 4.1 All clients undergo sputum microscopy.
(Possible indicators: NTP cards are reviewed for performance of sputum microscopy.)
- 4.2 If sputum microscopy facilities are not available in the TB DOTS Center, policies and procedures for referring clients to accessible centers are in place and implemented.
(Possible indicators: List of TB DOTS Center-identified microscopy centers; referral guidelines accessible to staff)
- 4.3 The TB DOTS Center plans and implements policies and procedures for assuring the quality of sputum microscopy results.
(Possible indicators: Documented quality control procedures and results of quality control testing)
- 4.4 External providers of sputum microscopy are contracted based on policies and procedures that include accreditation status and the presence of quality control systems.
(Possible indicators: Filed copies of accreditation status and quality control testing results of TB DOTS Center-identified microscopy centers.)
5. The TB DOTS Center clients have continuous access to safe and effective anti-TB medications throughout the duration of their treatment.

Criteria:

- 5.1 The TB DOTS Center has developed and implemented policies and procedures for assuring a continuous supply of TB drugs to all its clients for the entire six months duration of therapy.
(Possible indicators: TB drugs with buffer stock adequate for its registered and targeted patients; procedures for conducting drug inventory, requisition, purchasing, replenishment of stocks, etc)
- 5.2 The TB DOTS Center has developed and implemented policies and procedures for assuring the quality and safety of its TB drugs.
(Possible indicators: Documented procedures for gross testing of drug quality)

Management and information systems

Goal: The management, staff and patients adhere to clear and collaboratively developed policies and procedures for the efficient operation of the TB DOTS Center.

Standards:

6. Policies and procedures for providing care to clients are developed, disseminated and implemented.

Criteria:

- 6.1 Flow charts of patient processing from entry to separation are accessible to patients and staff.

- (Possible indicators: Prominently displayed patient flow charts, directional signages etc.; easily accessible DOTS manuals; patient defaulter tracing guidelines)*
- 6.2 Criteria and procedures for patient referral are accessible to patients and staff.
(Possible indicators: easily accessible referral guidelines; referral map)
- 6.3 Criteria and procedures for selecting and assigning DOTS partners are accessible to patients and staff.
(Possible indicators: written procedures for assigning DOTS partners)
- 6.4 Policies and procedures for identifying and working with external groups in providing DOTS services are developed and implemented.
(Possible indicators: Memorandum of understanding with external groups or partners with clear delineation of roles; policies and procedures for liaising with designated PPM coordinating body)
7. Policies and procedures for managing patient information are developed, disseminated and implemented.
- Criteria:
- 7.1 Each patient is uniquely identified from entry and throughout the course of management. (What about inter-center differentiation of patients and accommodation in a National TB Database? There must be norms for minimum dataset and unique identifier.)
- 7.2 The TB DOTS Center maintains a database of patient records and related registries and enables the staff to easily access these databases.
(Possible indicators: NTP forms, TB lab registry, TB patients registry)
- 7.3 Policies and procedures for ensuring the security and confidentiality of patient information are disseminated and followed.
(Possible indicators: written procedures for accessing any information related to the TB DOTS Center operations; written procedures for releasing patient information)

Human resources

Goal: The TB DOTS Center staff provide efficient and competent DOTS services.

Standards:

8. The TB DOTS Center has an adequate number of qualified personnel skilled in providing DOTS services.

Criteria

8.1 The following constitute the minimum TB DOTS Center personnel

- 8.1.1 TB DOTS Center administrator
- 8.1.2 Physician
- 8.1.3 Full time medical technologist
- 8.1.4 Full time nurse or midwife
- 8.1.5 Diagnostic committee members if applicable
- 8.1.6 Part time accountant
- 8.1.7 Drug supply manager

(Will a pharmacist be required for management and dispensing of DOTS drugs, as required by Pharmacy Law, which bans dispensing physicians?)

8.2 Personnel follow clear job descriptions, responsibilities and accountabilities.

(Possible indicators: Administrative manual with duties, responsibilities and accountabilities of all personnel; contracts of employment whenever appropriate)

8.3 Personnel receive up to date training based on training needs assessment.

(Possible indicators: Certificates of DOTS training from DOTS providers; certificate of TB microscopy training from NTP; Note: Training requirements must be specific for the personnel concerned, for example 5 days sputum microcopy training by RITM/JICA/Regional DOH laboratory for medical technologists. One may also want to set re-training requirements for those who were oriented to NTP before 1997, before DOTS was introduced by DOH, plus a refresher course every so often.)

Certification of DOTS professional providers (referring doctors)

DOTS professional providers can be divided into 2 categories:

- (1) DOTS Center professional provider-refers to the staff providing service in the certified DOTS center
- (2) DOTS certified referring health provider- refers to the physician referring to the DOTS center

Goals of certification

Certification is a process that assures the general public and payers of health care that a DOTS professional provider is capable of providing safe and effective DOTS services to TB patients. Despite evidence of its effectiveness in treating TB, DOTS is a relatively new intervention that has not been fully institutionalized and integrated into the health care system. Certification aims to standardize the provision of DOTS by imposing a uniform set of standards and criteria governing the performance of DOTS providers. Compliance with these standards and criteria is an excellent starting point on which the accreditation process of PHIC can begin.

The DOTS Center professional provider is expected to deliver quality DOTS service to patients availing of the facility. The DOTS referring health provider on the other hand is usually a general physician or specialist referring his patient to the DOTS Center. The latter is expected to have at least gone through a basic 8 hour course and workshop on DOTS to be provided by DOH, PhilCAT or its affiliate societies.

General eligibility requirements for certification

To be eligible for certification, a DOTS Center health provider must meet the following requirements

- The provider must possess current licenses that are relevant to the practice of his profession.
- The provider must be willing to provide DOTS service to TB patients.
- The provider must be willing to assume responsibility and be held accountable for his performance.

Purpose of certification survey

- *Proof of capability*

The certification survey is a process that determines the degree to which a DOTS professional provider complies with the minimal basic requirements for the safe and effective provision of DOTS services to TB patients. These initial requirements are regulatory in nature and are contained in the core standards for certification. Although

they are not meant to limit health professionals from acquiring further training and skills that are appropriate to the health needs of his clients, compliance with them does provide solid proof that DOTS providers are capable of further improvement of the quality of their services.

- ***Demonstration of ongoing performance improvement***

For DOTS Center professional providers to maintain certification, PhilCAT and PHIC will expect them to demonstrate compliance with the standards of the Leadership and Management and Human Resources Management clusters of standards of the *Philippine Health Insurance Corporation BenchBook of Performance Improvement (PhilHealth BenchBook)* as suitably amended for TB-DOTS Centers. These standards expect initially certified DOTS providers to integrate process and outcomes documentation, evaluation and action to improve care in his routine performance.

(Is a survey required for this or will a desk review suffice?)

Scope of certification

The scope of initial certification includes all the initial certification standards. Re-certification includes the *PhilHealth BenchBook* standards that are relevant to health care professionals. (Why wait three years for re-certification for providers when you require one year for centers, and the team would be at the center anyway? One may call it full certification after one year of initial provider certification, then recertification can happen every three years.)

Outcomes of certification process

The Certification Committee of PhilCAT makes certification decisions based on the results of the certification survey. A DOTS center provider can receive one of the following certification decisions:

- ***Certified***

A certification decision that results when a DOTS professional provider demonstrates acceptable compliance with the core standards for initial certification and / or re-certification.

- ***Not certified***

A certification decision that results when a DOTS professional provider consistently fails to demonstrate compliance with the core standards for initial and / or re-certification, when PhilCAT withdraws the certification for other reasons or when the professional provider voluntarily withdraws from the certification process.

Certification awards

Certified DOTS professional providers receive both the results of the certification survey and the PhilCAT certificate. DOTS referring health provider will receive the PhilCAT certificate of DOTS training.

Length of certification award

Certification awards have three years effectivity.

Information accuracy and truthfulness

The professional provider must at all times provide accurate and truthful information in the certification process. If the provider falsifies information relevant to his application for certification, either by commission or by omission, the certification will be immediately terminated or for applicants for initial certification, the provider will be ineligible for re-evaluation for at least one year. Falsification of information involves modifying, adding or deleting information for the purpose of misrepresentation.

Transparency and accountability

PhilCAT shall conduct the certification process with pre-defined decision making rules and administrative procedures. Deliberation proceedings will be fully documented and stakeholders can expect that the entire process shall be fully open for scrutiny whenever this is required. PhilCAT is accountable to PHIC for the quality of its certification process and will provide the latter with regular updates of its certification activities as well as additional information if so requested.

How to apply for certification

Any health professional that fulfills the general eligibility criteria for certification may fill up and submit an application for certification available at the PhilCAT or PHIC office or website. The application form requires the applicant to provide PhilCAT with essential information including his name, address, educational background and institutional affiliations.

PhilCAT will also require submissions of proof that the professional provider has complied with all the standard legal and statutory requirements relevant to his practice. This will include licenses and permits issued by the PMA, the specialty societies, PHIC and local government agencies.

Providers may apply in either electronic or paper format to:

Philippine Coalition Against Tuberculosis (PhilCAT)

Secretariat: Quezon Institute Compound E. Rodriguez Avenue, Quezon City

Telefax (632) 7498990

Email address: philcat@pacific.net.ph

The certification decision process

Certification decisions are made by the PhilCAT Certification Committee based on the findings of the survey team. The certification decision is either (a) certified or (b) not certified. All unresolved issues and all additional requirements must be addressed by the professional provider before a certification decision is made.

The re-certification decision will be based on an algorithm that considers minimal passing scores on the certification standards. Each standard is scored “fully met”, “partially met” or “not met”. Depending on whether the standards are in the core list or not, the individual standard scores are then weighted and the resulting products are aggregated. Consideration of both the individual weighted standard scores and the aggregate score will indicate whether the provider has met the minimum expected compliance with the certification standards.

Appeals of decision not to certify

Upon receipt of the decision not to certify, the provider has one week to notify the PhilCAT Board in writing of its intention to appeal the decision. The provider has an additional four weeks to submit additional appropriate information and new data to justify its appeal. The PhilCAT Board will only act on the appeal and consider amending the decision upon receipt of this fresh information; otherwise, it shall consider the decision as acceptable to all parties concerned. The Board considers the appeal and the supporting information in making a final determination of the certification status.

Cost of certification

The provider shall pay a certification processing fee which covers for the following:

- Processor's time for reviewing the application for certification or re-certification
- Administrative handling fees for actual processing

The fee is payable upon application for certification and is non-refundable regardless of the certification decision.

Confidentiality

PhilCAT shall not publicly release any finding generated by the certification process or any information about the providers. The only information that PhilCAT will publicly release is the providers' certification status, that is, whether or not a particular provider is certified and, possibly, the aggregate score.

Maintenance of certification

A certification award is valid for three year unless revoked by PhilCAT or voluntarily surrendered by a certified center. PhilCAT will not automatically renew the certification status after three years. Rather the provider must again apply for re-certification, satisfy all additional conditions that may be required of him and provide sufficient evidence of compliance with all PhilCAT standards.

The TB DOTS Center has the sole responsibility of seeing to it that all its referring providers have currently valid PhilCAT certification. Any change in certification status of any provider must be reported by the TB DOTS Center to PhilCAT within two weeks after status change under pain of revocation of its certification. This will help prevent the DOTS center from paying providers who lose their certification status in-between certification decisions.

Re-certification based on the *PhilHealth BenchBook* standards

Effective DOTS service provision is essentially based on special attention to the processes of following-up patients in active treatment to ensure compliance and good clinical outcomes. Compliance with the initial certification standards do not necessarily ensure that the goals of DOTS will be achieved. Initially certified professional providers must therefore move quickly from the paradigm of proving capability to the paradigm of

proving quality. Compliance with the relevant clusters of standards that PHIC uses for accrediting health care organizations, after appropriate adaptation, will bring TB-DOTS providers within the new quality framework of PHIC. Quality consists of doing the right things the right way. To be re-certified, TB-DOTS providers must demonstrate that they are documenting, evaluating and taking action to improve their processes of patient care and clinic management. **For specific *PhilHealth BenchBook* standards that are applicable to TB-DOTS providers, please see the next section on quality assurance for TB-DOTS Centers and providers.**

- ***Re-certification review***

A PhilCAT reviewer will be assigned to review a professional provider's submitted evidence of compliance to both initial certification and the adapted *PhilHealth BenchBook* standards. Each standard is graded "met", "partly met" or "not met".

- ***Re-certification decision processes***

Using a new set of scoring, weights and aggregation rules, the decision to re-certify or not to re-certify is arrived at by the PhilCAT reviewer and approved by the PhilCAT Certification Committee. Procedures for communicating and fulfilling conditions for re-certification and for appeals of decisions no to re-certify are the same as those for initial certification.

Public disclosure of certification status of TB DOTS Providers

PhilCAT is committed to making relevant and accurate information about surveyed TB-DOTS Centers available to the public. Such information is a powerful motivator for TB-DOTS Centers to continuously improve their services. Such information also educates the public about the role of certification in ensuring quality of services. Finally, health care consumers and payers stand to make better informed choices if the results of the initial certification and re-certification are made known to them.

However, in order to preserve the openness and trust between PhilCAT and the TB-DOTS professional providers, details of the re-certification review findings will NOT be released. Only the certification status of the providers will be publicly disclosed. Please refer to the section on Confidentiality for more details.

The TB-DOTS professional provider standards for initial certification

Goal: The TB-DOTS professional provider is able to give competent and up-to-date DOTS services to his clients.

Standards:

1. The TB-DOTS professional provider complies with all the regulatory requirements for safe and effective practice.

Criteria:

- 1.1 The TB-DOTS provider has current PRC license.
- 1.2 The TB-DOTS provider has current PHIC accreditation.

2. The TB-DOTS professional provider possesses up-to-date knowledge and skills in the provision of DOTS service.

Criteria:

- 2.1 The TB-DOTS provider has attended the TB-DOTS training conducted by PhilCAT / DOH or other PhilCAT / DOH-recognized training institutions.(could also be conducted by DOH or other providers as long as they conform to approved syllabus?)
- 2.2 The TB-DOTS provider has attended other continuing medical education and skills building sessions conducted by PhilCAT and other relevant agencies.