

APPENDIX E: MODEL BATCH CERTIFICATE

General Instructions

Please refer to the explanatory notes below for full instructions on how to complete this form and information on the implementation of the scheme. These forms are suitable for generation by computer. They should always be submitted as a hard copy, with responses printed in type rather than handwritten. Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Manufacturer's/Official ¹ Batch Certificate of a Pharmaceutical Product	
This certificate conforms to the format recommended by the World Health Organization	
1.	No. of certificate:
2.	Importing (requesting) authority:
3.	Name of product: ²
3.1.	Dosage form:
3.2.	Active ingredient(s) and amount(s) per unit dose:
3.2.1.	Is the composition of the product identical to that registered in the country of export? yes/no/not applicable ³ (<i>key in as appropriate</i>) If no, please attach formula (including excipients) of both products.
4.	Product license holder ⁴ (name and address):
4.1.	Product license number: ⁴
4.2.	Date of issue: ⁴
4.3.	Product license issued by: ⁴
4.4.	Product certificate number: ^{4,5}
5.1.	Batch number:
5.2.	Date of manufacture:
5.3.	Shelf life (years):
5.4.	Contents of container:
5.5.	Nature of primary container:
5.6.	Nature of secondary container/wrapping:
5.7.	Specific storage conditions:
5.8.	Temperature range:
6.	Remarks: ⁶
7.	Quality analysis:
7.1.	What specifications apply to this dosage form? Either specify the pharmacopoeia or append company specifications. ⁷
7.1.1.	In the case of a product registered in the exporting country, have these company specifications ⁷ been accepted by the competent authority? yes/no (<i>key in as appropriate</i>)
7.2.	Does the batch comply with all parts of the above specifications? yes/no (<i>key in as appropriate</i>)
7.3.	Append certificate of analysis. ⁸

**COMPENDIUM OF INDICATORS FOR MONITORING AND EVALUATING
NATIONAL TUBERCULOSIS PROGRAMS**

It is hereby certified that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and exporting countries.	
Name and address of authorized person:	
Telephone number:	Fax number:
Signature of authorized person:	
Stamp and date:	

Explanatory Notes

Certification of individual batches of a pharmaceutical product is only undertaken exceptionally by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera, and biological products. For other products, the responsibility for any requirement to provide batch certificates rests with the product license holder in the exporting country. The responsibility to forward certificates to the competent authority in the importing country is most conveniently assigned to the importing agent. Any inquiries or complaints regarding a batch certificate should always be addressed to the competent authority in the exporting country. A copy should be sent to the product license holder.

¹ Strike out whichever does not apply.

² Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

³ "Not applicable" means that the product is not registered in the country of export.

⁴ All items under 4 refer to the product license or the certificate of a pharmaceutical product issued in the exporting country.

⁵ This refers to the certificate of a pharmaceutical product as recommended by the World Health Organization.

⁶ Indicate any special storage conditions recommended for the product as supplied.

⁷ For each of the parameters to be measured, specifications give the values that have been accepted for batch release at the time of product registration.

⁸ Identify and explain any discrepancies from specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a given batch has been released, without necessarily giving the results of testing. The testing results are contained in the manufacturer's certificate of analysis.

**APPENDIX F: HUMAN RESOURCE DEVELOPMENT
ASSESSMENT FORMS**

The following assessment forms pertain to Indicator 3.9 (for district, regional, and central levels) and Indicator 9.3. A full description of the HR country assessment is available in work by Bergstrom and Plamer.¹

Instructions for filling in assessment forms 1 through 4

Assessment Form 1

Follow the steps below to assess the needs for different types and numbers of staff at **peripheral-level** government health facilities:

- Determine the major tasks to be performed at peripheral-level government health facilities (This will most likely be limited to three major tasks, namely, detection, diagnosis, and treatment of a TB patient.)
- Estimate time needed to perform each of these tasks
- Determine which type of staff is performing each task
- Determine the existing type and number of the staff implementing the tasks at peripheral-level government health facilities
- Determine the workload on the basis of the number of patients diagnosed
- Determine the current work time available for all patient care, and then the work time dedicated to TB control, for each type of staff at peripheral-level government health facilities (specialized/multipurpose staff)
- Determine discrepancy, if any, between available staff and required staff if 70% case detection were achieved.

Assessment form 1 consists of four columns. The first column lists the task being assessed; the second column provides an estimate of time needed; the third column provides space for the country-specific estimate, which may or may not differ from the estimate shown in the second column; and the last column provides space for listing the type of staff performing the task.

¹ Bergstrom K, Plamer K. *Questionnaire to assess the current staffing situation and future staff needs for TB control in high burden countries*. Geneva, Stop TB Department, World Health Organization, March 2003.

Assessment Form 2

Use the core tasks listed below to assess the staff needs at the **district level**. There should be sufficient staff capacity to coordinate all of the following core tasks of DOTS implementation:

- Prepare decentralized strategic plans for TB control
- Manage budgets and finances
- Plan and manage drug supplies and equipment
- Maintain treatment registers
- Conduct supervisory visits
- Ensure that lower level staff are competent to implement TB control services
- Monitor DOTS implementation
- Support laboratory services
- Coordinate advocacy activities
- Coordinate activities with partners.

Assessment form 2 consists of three columns. The first column lists the core tasks as indicated above, the second column provides space for noting who is currently responsible for implementing each core task, and the third column provides space for listing the number of additional staff members needed for each task. Space is provided below the columns for describing why staff members are needed.

Assessment Form 3

Use the core tasks listed below to assess the staff needs at the **regional level**. There should be sufficient staff capacity to coordinate all of the following core tasks of DOTS implementation:

- Prepare decentralized strategic plans for TB control
- Manage budgets and finances
- Plan and manage drug supplies and equipment
- Conduct supervisory visits
- Ensure that lower level staff are competent to implement TB control services
- Monitor DOTS implementation
- Support laboratory services
- Coordinate advocacy activities
- Coordinate activities with partners.

Assessment form 3 consists of three columns. The first column lists the core tasks as indicated above, the second column provides space for noting who is currently responsible for implementing each core task, and the third column provides space for listing the number of additional staff members needed for each task. Space is provided below the columns for describing why staff members are needed.

Assessment Form 4

Use the core tasks listed below to assess staff capacity and need at the **central level**. In high-burden countries, dedicated staff members are generally needed for all of the areas listed. There should be sufficient staff capacity to coordinate all of the following core tasks of DOTS implementation:

- Strategic planning, including policy framework and donor coordination
- Financing
- Human resource development
- Drug management
- Technical support to regions and districts
- Coordination with laboratory services
- Monitoring and evaluation
- IEC
- Advocacy
- Operational research
- Intersectoral collaboration and coordination.

Assessment form 4 consists of three columns. The first column lists the core tasks as indicated above, the second column provides space for noting who is currently responsible for implementing each task, and the third column provides space for listing the number of additional staff members needed for each task. Space is provided below the columns for describing why staff members are needed.

ASSESSMENT FORM 1

Use this worksheet to calculate time estimates for treatment of one new sputum smear-positive tuberculosis patient (Indicator 9.3)

Task	General estimate of time needed	Your estimate of time needed	Type of staff performing task in country
1. First visit to outpatient, patient suspected of having TB, smear examination	15 min		
2. Second visit, diagnosis confirmed, patient started on treatment	15 min		
3. Initial phase, 56 doses of observed treatment	56 × 5 min = 280 min		
4. Visit for first follow-up sputum examination	10 min		
5. Continuation phase, 48 doses of observed treatment	48 × 5 min = 240 min		
6. Visit for second follow-up sputum examination	10 min		
7. Visit for third follow-up sputum examination	10 min		
8. Last visit to outpatient to confirm treatment finalized	10 min		
9. Additional time for information, follow-up, defaulter tracing, etc., an average of 60 min per patient (as well as compensating time spent for sputum taken of patients with suspected TB but diagnosis not confirmed)	60 min		
10. Total average time for treatment of new sputum smear-positive tuberculosis patient	10 h and 50 min or about 11 h		Box 1

ASSESSMENT FORM 2

Determine the current staff capacity and additional staff needed for each task at the **district level** of the NTP (Indicator 3.9)

Task	Current implementation of tasks (indicate person and title)	Number of additional staff needed (if any)?*
1. Prepare decentralized strategic plans for TB control		
2. Manage budgets and finances		
3. Plan and manage drug supplies and equipment		
4. Maintain treatment registers		
5. Conduct supervisory visits		
6. Ensure that lower level staff are competent to implement TB control services		
7. Monitor DOTS implementation		
8. Support laboratory services		
9. Coordinate advocacy activities		
10. Coordinate activities with partners		

*Please summarize why additional staff are needed and whether there are any constraints to hiring additional staff:

ASSESSMENT FORM 3

Determine the current TB coordinator capacity and additional staff needed for each task at the **regional level** of the NTP (Indicator 3.9)

Task	Current implementation of tasks (indicate person and title)	Number of additional staff needed (if any)?*
1. Prepare decentralized strategic plans for TB control		
2. Manage budgets and finances		
3. Plan and manage drug supplies and equipment		
4. Conduct supervisory visits		
5. Ensure that lower level staff are competent to implement TB control services		
6. Monitor DOTS implementation		
7. Support laboratory services		
8. Coordinate advocacy activities		
9. Coordinate activities with partners		

*Please summarize why additional staff are needed and whether there are any constraints to hiring additional staff:

ASSESSMENT FORM 4

Determine the current staff capacity and additional staff needed for each task at the **central level** of the NTP (Indicator 3.9)

Task	Current implementation of tasks (indicate person and title)	Number of additional staff needed (if any)?*
1. Strategic planning, including policy framework and donor coordination		
2. Financing		
3. Human resource development		
4. Drug management		
5. Technical support to regions and districts		
6. Coordination with laboratory services		
7. Monitoring and evaluation		
8. IEC		
9. Advocacy		
10. Operational research		
11. Intersectoral collaboration and coordination		

*Please summarize why additional staff are needed and whether there are any constraints to hiring additional staff:
