



Ukrainian Center for Socially  
Dangerous Disease Control of  
The Ministry of Health of Ukraine

**Ministry of Health of Ukraine**

**Ukrainian Center for Scientific Health Care Information,  
Patenting and Licensing**

# **USING THE CLINICAL ASSESSMENT FOR SYSTEMS STRENGTHENING (CLASS) TECHNIQUE FOR MONITORING THE HIV/AIDS RESPONSE PERFORMANCE AT UKRAINIAN HEALTH CARE FACILITIES**

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**GUIDELINES**

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Ministry of Health of Ukraine

Ukrainian Center for Scientific Health Care Information,  
Patenting and Licensing

“APPROVED”

Director, Public Health Department  
Ministry of Health of Ukraine

\_\_\_\_\_ S. I. Ostashko  
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**Using the Clinical Assessment  
for Systems Strengthening (CLASS) Technique for  
Monitoring the HIV/AIDS Response Performance at  
Ukrainian Health Care Facilities  
(Guidelines)**

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## ABBREVIATIONS AND ACRONYMS

|           |  |
|-----------|--|
| ART       | Antiretroviral therapy   |
| AIDS      | Acquired immune deficiency syndrome  |
| CDC       | Centers for Disease Control and Prevention                                       |
| CLASS     | Clinical Assessment for Systems Strengthening                                    |
| CSW       | Commercial sex worker  |
| CQI       | Continuous quality improvement   |
| EMR       | Electronic medical records   |
| EV        | Extended visit   |
| HCF       | Health care facility   |
| HCT       | HIV counseling and testing   |
| HHS       | The U.S. Department of Health and Human Services                                 |
| HIV       | Human immunodeficiency virus   |
| HRSA      | Health Resources and Services Administration                                     |
| IC        | Infection control  |
| ISO       | International Organization for Standardization                                   |
| IT        | Information technology   |
| I-TECH UW | International Training and Education Center for Health, University of Washington |
| MARP      | Most-at-risk patient   |
| MIS       | Management information system  |
| MOH       | Ministry of Health   |

|        |   |
|--------|---|
| MSM    | Men who have sex with men   |
| NEP    | Needle exchange point   |
| NGO    | Non-governmental organization   |
| PEP    | Post-exposure prophylaxis   |
| PEPFAR | The U.S. President's Emergency Plan for AIDS Relief                                 |
| PHC    | Primary health care   |
| PLHIV  | People living with HIV  |
| PMTCT  | Prevention of mother-to-child transmission  |
| PWID   | People who inject drugs   |
| RV     | Rapid visit   |
| SI     | State Institution   |
| SOP    | Standard operating procedure  |
| STI    | Sexually transmitted infection  |
| TB     | Tuberculosis  |
| UCSDDC | Ukrainian Center for Socially Dangerous Diseases Control (under the MOH of Ukraine) |

## INTRODUCTION

Given the current state of Ukrainian health care system reform, quality of care is a pivotal criterion for performance of facilities at all levels. Adopted in 1996 at the conference of WHO European region health ministers, the Ljubljana Charter on Reforming Health Care defines continuous improvement in quality of health care, including its cost-effectiveness, as among the fundamental principles of health care reform.

As of today, improvement in quality of health care services in Ukraine remains a current issue on the agenda. Resolution of the Cabinet of Ministers of Ukraine No. 389, dated 2 February 2011, “On Approval of the Program on Development of Investment and Innovative Activities in Ukraine,” identified key areas for health care reform—including, but not limited to, improvement in quality of, and access to, health care services. That said, the issue of health care quality management and evaluation is one of the most crucial for the Ukrainian health care system (in accordance with the Concept on Health Care Quality Management in the Ukrainian Health Care Sector Until 2020, approved with Order of the Ministry of Health of Ukraine No. 454, dated 01 August 2011).

The major purpose of conducting a Clinical Assessment for Systems Strengthening (CLASS) is to explore best practices of facilities that deliver health care and social management services to people living with HIV (PLHIV), and to single out areas that require improvement, with objectives of strengthening systems of available services, improving the quality of services, and expanding their range and scope. A CLASS assessment pays special attention to the following issues: efficient utilization and management of available resources, management and administration of HIV response programs, securing the financial sustainability of the health care facility, strengthening human resources and managerial capacities, and ensuring comprehensive, quality clinical services, including HIV counseling and testing (HCT).

These Guidelines present information on the CLASS tools, as well as an algorithm for conducting a CLASS assessment, including descriptions of processes taking place at the planning and preparation stages, and of the assessment itself.

The Guidelines also present general principles and key recommendations on organizing and conducting CLASS assessments of health care facilities and entities that provide other services in the field of prevention and treatment of HIV.

CLASS is especially relevant in this period, when the health care system is being reformed, cost-effective solutions are being sought, the patient rights movement is building, and requirements for certification of health care facilities are mounting.

The Guidelines, based on the international CLASS tools and methodologies adapted for use in Ukraine, were developed by the Ukrainian Center for Socially Dangerous Disease Control (UCSDDC), under the Ministry of Health (MOH) of Ukraine, in collaboration with the International Training and Education Center for Health (I-TECH), part of the Department of Global Health at the University of Washington (UW). The Health Resources and Services Administration (HRSA), in conjunction with I-TECH, drafted the CLASS tools with the objective of contributing to long-term sustainability and government support of HIV prevention and treatment programs. I-TECH played an instrumental role in tailoring the technique to the Ukrainian context, with financial support from the U.S. Centers for Disease Control and Prevention (CDC) and HRSA, within the framework of implementation by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in Ukraine.

The Guidelines are meant as a reference document for CLASS reviewers, to assist them in planning and conducting facility assessments, as well as for the managers and professionals (e.g., infectious disease doctors, epidemiologists) at those facilities.

## **SECTION 1. DESCRIPTION OF THE CIASS TECHNIQUE**

CIASS is a technique for qualitative assessment of a health facility or organization, with the ultimate goal of determining best practices, defining a participating organization's capacity and achievements, assessing capacity-building needs, and seeking ways and resources to provide sustainable, continuous quality services. Unlike traditional approaches, CIASS is not an audit; it entails an assessment process involving not only reviewers, but all parties, including representatives of the facility under assessment.

Assessments based on the CIASS technique include:

- Detailed, profound qualitative assessments of the administrative, financial, HR, and technical capacities of facilities implementing programs for prevention, diagnosis, treatment, care, and support of PLHIV that are paid for out of state and local budgets, and/or with support from international technical assistance projects, other donors, and charity organizations.
- Determining areas of activity that require strengthening and/or technical assistance in order to ensure sustainability, consistency, and appropriate quality of services.
- Providing recommendations on strengthening capacity at facilities.
- Active planning by representatives of participating facilities to develop practical, feasible actions to strengthen the system of health care and social services for PLHIV, and develop steps for their implementation.
- Providing information to stakeholders on technical assistance needs, identifying local resources to help meet those needs, and, when necessary, planning technical assistance for further strengthening capacities and enhancing quality of services.
- Elaborating on actions to develop and implement continuous quality improvement systems for ongoing refinement of services.

The CLASS tool comprises modules, topic-specific guides for quality assessment, that are used by CLASS reviewers when conducting in-depth group and individual interviews, reviewing key documents, and verifying information.

The following modules have been adapted for use in Ukraine:

**1) *Administrative Module*** (Annex 1).

The administrative module is designed to assess administration capacity and the quality of program and resource management. It looks at the facility's organizational structure; program administration and facility management; strategic and short-term planning; management of available resources; supervision of implementation of program commitments; HR policy and procedures; licensing and certification; administration support to ensure the facility can function and provide services in times of crisis; clear division of functions, responsibilities, and subordination; services quality provision and control; and cooperation and use of management information systems.

**2) *Financial Module*** (Annex 2).

The financial module is designed to assess the financial sustainability of the facility, the programs it has under implementation, and its financial management. It looks at management of expenditures and revenues; payroll accounting and determination of rewards; accounts and payments; accounting systems; accounts payable and cash flow; fixed assets; monitoring of inventory and procurement procedures; delivery procedures; and breakdown and management of expenditures.

**3) *HIV Counseling and Testing (HCT) Module*** (Annex 3).

The HCT module is designed to assess the quality of administration of HCT processes and procedures. It looks at HCT service delivery, as well as such issues as cooperation with other organizations, and referral systems; public mobilization systems; awareness-raising and preventive activities among the public and HIV risk groups; and systems for HCT quality control and assurance.

**4) *Clinical Module*** (Annex 4).

The clinical module is designed to assess staffing capacity, as well as the range and quality of health care services the facility provides in the areas of HIV prevention,

diagnosis, and treatment. It looks at the human resources and technical capacity available for clinical services, the efficiency and completeness of clinical activities, mentoring support for clinical work, monitoring and continuous quality improvement, support for decentralization, and technical assistance needs.

UCSDDC, the main national coordinator of CLASS, is the certifying body for CLASS reviewers, and may introduce additional modules to the CLASS tool as needed.

The Oblast and Kyiv City AIDS centers (AIDS centers) coordinate CLASS assessments at the regional level.

Only specialists trained and certified as CLASS reviewers may conduct assessments. (See Annex 5 for a list of certified CLASS reviewers. The recommended composition of the CLASS review team, the qualification requirements for team members, and the team's functional responsibilities are discussed in Annex 6.)

Assessments based on the CLASS technique are important components in the range of activities for improving quality of health care services. Based on assessment findings, facility administration is given the opportunity to develop and implement corrective measures to ensure ongoing improvement in the quality of health care services.

CLASS review findings can be used to justify the need for strengthening capacity, and for technical and other assistance from state and non-government spending units, to ensure sustainability, efficiency, and quality of HIV services.

## SECTION 2. CLASS ASSESSMENT STAGES

The CLASS assessment process consists of six stages:

- Initiation
- Planning and preparation
- The assessment itself
- Action planning based on the results of the assessment
- Preparation of the assessment report
- Initiation of a cycle for continuous quality improvement in services provided by the facility or organization

The duration of each stage may vary depending on whether the assessment is a facility's first assessment or a follow-up, as well as on the number and size of facilities to be assessed. If it is a follow-up assessment, the main focus is often on how well the facility has implemented recommendations from the previous assessment, although additional strengths and areas for improvement may also be identified.

The time required to complete an assessment of the health care facility also depends greatly on the type of facility or organization being assessed; the size of the facility, and the scope of services it offers; and how many of the CLASS modules are used in the assessment process.

The typical amount of time recommended for assessment of certain facilities is as follows:

- Trust rooms and primary health care facilities: one working day.
- City and Oblast AIDS Centers: two to three working days.

### 2.1. Stage One: Assessment Process Initiation

The assessment may be initiated by national/regional coordinators, or by the facilities/organizations providing HIV services.

If the assessment is initiated by the facilities/organizations providing HIV services:

- The facility/organization shall submit a written request to the regional assessment coordinator. (See Annex 7 for a sample letter; email addresses of coordinators and CIASS reviewers are listed in Annex 5.)
- The regional coordinator shall appoint a CIASS review team leader as agreed with the UCSDDC.

If the assessment is initiated by the national/regional coordinator:

- The coordinator (as agreed with the UCSDDC) shall designate the facility/organization(s) to be assessed. Assessment of the facility shall be initially decided upon with the director of the facility/organization (a sample letter is provided in Annex 8).
- The national coordinator shall appoint the regional coordinator for implementation of the CIASS process.
- The regional coordinator (as agreed with the UCSDDC) shall appoint a CIASS review team leader.

Stage One lasts from one to two weeks.

## **2.2. Stage Two: Assessment Planning and Preparation**

### ***2.2.1. Formation of a review team***

The regional/national coordinator of the assessment determines the main goal, objectives, and scope of the assessment. S/he shall form a team of reviewers based on the objectives identified, and the modules to be used in the assessment. (The qualifications and functions of review team members are discussed in Annex 6.) The assessment must involve reviewers in the Administration and Finance modules. The need for participation of reviewers in the Clinical and HCT modules will depend on the services offered by the facility/organization to be assessed.

A leader shall be selected from among the review team members, and formally appointed as coordinator.

### ***2.2.2. Review of documents prior to the assessment***

The team leader, together with reviewers, shall develop a list of specialists to be involved in the assessment process, and a list of documents to be analyzed prior to the site visit (Annex 9).

The team leader shall send (either by post or email) an information brief/letter to the facility to be assessed (Annex 10). The brief/letter shall contain key information about the goal, objectives, and methods of the assessment, as well as the lists of documents to be reviewed and professionals to be involved in the assessment. Copies of these documents shall be sent by the facility, whether in hard-copy form or by email (for scanned documents), to the review team leader. The team leader shall review and analyze the documents, and distribute copies to other members of the team.

### ***2.2.3. Planning the assessment***

When assessing a health care facility, two introductory meetings are planned: one with the health facility director and employees, and the other with the health care department of the oblast or city state administration.

The CLASS team leader shall coordinate the date, time, and place of the introductory meetings with the director of the facility and CLASS reviewers, as well as with the health care department (if a health care facility is to be assessed); and, in cooperation with the director of the facility and CLASS reviewers, schedule the dates, times, and locations of the debriefing sessions (one session with the director of the facility, and another session with facility employees).

The CLASS team leader and facility director shall coordinate the date, time, and location of the post-assessment action-planning meeting with both the regional partner organizations and the review team. The facility director shall send official invitations to the partner organizations to participate in this session.

#### ***2.2.4. Development of the assessment implementation program***

Prior to the CLASS assessment, the director of the facility shall inform employees about the goals, methods, and timetable of the upcoming assessment, and prepare a presentation to provide an overview of the facility to be assessed (see Section 2.3.1 below).

The review team leader shall:

- Develop the CLASS assessment timetable, and coordinate with the facility and the regional/national coordinator (Annex 11).
- Send the designated facility CLASS assessment program to both the director of the facility and the review team.

Stage Two may last from two to three weeks.

### **2.3. Stage Three: Conducting the Assessment**

The duration of Stage Three depends on the number and level of the facilities to be assessed; Stage Three may last from one to three working days for each facility assessed.

This stage includes:

#### ***2.3.1. Conducting opening sessions***

Each assessment shall start with one or two opening sessions, depending on the level of health care services provided, and the number of facilities participating.

*The first opening session* is held at the facility, with all facility staff and review team members in attendance.

*The second opening session* is held with the health care department of the oblast or city state administration, with involvement of all assessment participants (as needed).

Each opening session is composed of two parts.

The first part of the opening session is conducted by the review team leader, and may last no longer than 15–20 minutes. This part includes:

- Expression of thanks to the head of the health care department of the oblast or city state administration, and/or the director of the participating health care facility for their time and cooperation.
- Introduction of the review team members to facility staff.
- Presenting information about the main goals of the review team visit.
- A general overview of the CLASS technique: description of processes, procedures, and tools.
- Discussion of the assessment scheme, timeline, and stages.
- Discussion of the format and timelines for the presentation of assessment findings, and possible ways of using them.

The second part of the opening session is led by the participating facility representative. It lasts about 10–15 minutes, and can include:

- History of the facility and its activities.
- Summary of the HIV epidemiological situation in the region.
- Description of the range of services being provided.
- Financial resources.
- Staffing.
- Number and breakdown of patients.
- Information systems.
- Strategic plans for facility development.
- The major challenges the facility faces in its main activities—e.g., those that have an impact on the quality and sustainability of the services it provides.

In the cases of oblast or city AIDS centers, trust rooms, or antiretroviral treatment (ART) sites, the opening sessions may be more detailed. The opening session at primary health care facilities shall last no longer than 15 minutes, and include only selected general issues.

The guidelines for the CLASS review team’s introductory sessions at a facility are described in detail in Annex 12.

### ***2.3.2. The facility tour***

After the opening sessions, the team takes a tour of the facility, following the patient pathway from entering the compound to the registry desk, and covering points of service delivery throughout the facility. This tour provides the review team members with information about the range, completeness, and accessibility of clinical and social services provided by the facility; confidentiality of service delivery; and infection prevention and control measures.

Review team members are advised to refrain from in-depth, module-specific questions during this tour, and to instead focus on broader issues that may be relevant to all reviewers.

If a health care facility is small, or a facility tour by all review team members may disrupt services, it is advisable to split the team by areas of activity and arrange separate tours.

If a health care facility has several departments/units that are geographically separate, then the tour may cover the major units only. Priorities for the tour should be identified and agreed upon by the review team members during the preparation stage.

### ***2.3.3. In-depth individual or group interviews with key staff identified during the preparation stage***

The staff members selected to participate shall be notified in advance, and be ready to spare time to answer reviewer questions.

Interviews may be conducted individually, or in small groups. When conducting interviews, reviewers should follow these recommendations:

- The reviewer(s) shall conduct interviews directly with staff providing services, not with facility/department/unit management. This will give a more accurate picture of actual services being provided, their scope, and their quality.
- Management shall not be present during in-depth interviews with employees. This will foster more comfortable conditions, and aid in obtaining more complete and reliable information.

- It is advisable to conduct interviews at service delivery points, rather than in separate conference/meeting rooms or offices. This will allow additional opportunities for reviewing documents directly on site, understanding client/patient flow, and getting a better sense of facility employees' working conditions.
- It is essential to create comfortable conditions for respondents during interviews. This can be facilitated by using open-ended questions, active listening, and avoiding judgmental comments or comments that indicate you are making assumptions about respondents and their work.
- If an interview is conducted jointly by several CIASS reviewers, it is important for the team to agree on its approach before the interview. For example, the interview could be conducted primarily by one interviewer, and then the others may put forth their questions for clarification after the initial line of questioning is complete. The lead interviewer should explicitly provide the co-reviewers with opportunities to ask questions.
- All CIASS reviewers shall start their interviews with open-ended questions. Let the respondent take his/her time to answer each question. Don't interrupt the respondent, even if the answers are redundant, or if it is difficult to separate relevant from irrelevant information. If you think of questions for clarification during the response, write them down, and then ask when the respondent finishes his/her answer.
- After the open-ended questions, it may be appropriate to ask specific questions for clarification, as needed, to obtain additional information.

The reviewer(s) shall use his/her own professional experience to guide the assessment; however, it is helpful to follow a logical flow of questions by using the modules to organize the interview for the specific area under assessment.

Below are interviewing recommendations for each assessment area.

## **Administration**

There are two key issues to focus on within the administrative module.

The first is to identify the main methods and mechanisms employed by management in managing the facility, assess the quality of managerial processes and continuous quality improvement in managerial decisions, and evaluate relationships among facility management and employees. Special attention shall be given to the system for identifying emerging problems, and the mechanisms for addressing them.

The second is to assess the facility's human resources. Based on interviews with staff representatives (it is advisable to interview at least three to five key staff members from different areas), the review team member shall develop a clear understanding their responsibilities and subordinate relationships at the facility.

## **Finance and program funding**

Specialists from the administrative and finance departments involved in budget generation and calculation, accounting, and reporting should be interviewed. The reviewer should particularly focus on the presence (or absence) of financial management policies/regulations; the system for ensuring compliance with these policies/regulations; the clear allocation of financial management roles and responsibilities; the review of expenditure (budget) planning procedures; the measures and procedures used for controlling and minimizing financial risk; the frequency/type of financial reporting to relevant executive and supervisory authorities; and the capacity to identify alternative sources of funding for long-term sustainability of the facility or organization.

## **Clinical services**

Interviews in the clinical area shall be conducted at service delivery points. Interviews are to be conducted directly in the workplace, with those staff members not performing their duties at that time.

Based on these interviews, the reviewer shall form a clear understanding of the range, integrity, and quality of clinical services provided; the system in place for quality improvement and monitoring; and the efficiency of the quality improvement system. In addition, the systems for referrals and linkages are assessed; along with the range, accessibility, and quality of laboratory services; inventory management systems; and infection prevention and control procedures.

### **HIV counseling and testing (HCT)**

Based on interviews, the reviewer shall obtain information about the system for providing HCT services. This system includes engagement of patients for testing, observance of national guidelines on HCT, and relevant documentation. Laboratory assessment is a mandatory component of the HCT review.

HCT is reviewed in close cooperation with clinical reviewer(s). It is important to assess the referral and linkage systems for sending clients/patients with positive HIV test results to receive further clinical and social services.

#### ***2.3.4. Review of the primary accounting, reporting, and other documents necessary for verification of obtained information***

Information obtained from in-depth interviews shall be verified by reviewing relevant documents, specifically accounting reports, foundation documents, primary clinical records and reports, and minutes of meetings.

When reviewing the minutes of meetings, it is advisable to look at several consecutive meetings to determine if actions and follow-up have been taken to address the issues raised. It is important to focus on both implemented and non-implemented recommendations, as well as on factors fostering and interfering with implementation.

The clinical module also includes a review of individual patient files. The reviewer shall look at files from various populations (e.g., adults, children, pregnant women), and, for each patient group, check files for patients who are currently on

ART, those who have not yet started ART, those who have died, and those who have dropped out of treatment.

### ***2.3.5. Debriefing sessions***

At the end of each assessment day, the review team leader shall hold an internal session with all review team members to discuss the following:

- Observance of the assessment plan for the day, including time limits.
- Issues that require additional clarification, verification, and concretization.
- Problems that review team members faced during the day, and their solutions.
- Discussion and preliminary agreement on strengths/best practices and areas for improvement identified that day.
- Plans for the next day.

Once the assessment is over, all the review team members shall hold an internal debriefing session to discuss their findings. They shall determine and concur on all findings, including strengths and areas for improvement. All assessment findings, without exception, shall be agreed upon by all review team members at the internal debriefing session before they are presented to facility management and employees.

After the internal debriefing session, the review team shall hold two debriefing sessions with facility representatives.

The first session should last about 15–30 minutes. Only the review team members and the director of the facility (or his/her authorized representative) shall take part. During this session, review team members share their findings with the director of the facility, and reach agreement on those findings to be presented to facility employees at the second debriefing session. Findings rejected by the head of the facility *shall not be presented* to facility employees. During this session, the director shall formulate his/her proposals for addressing the areas identified for improvement.

Both management and employees of the facility shall attend the second session, where the assessment findings are presented. While presenting their findings, review team members shall start with strengths and successful points, and finish with areas in need of improvement. Facility employees may ask questions for clarification, and offer proposals for addressing the areas identified for improvement. The review team shall answer all questions concerning the findings, and provide clear, detailed examples to illustrate them. This session should last from 40 to 90 minutes.

At the end of the session, the team leader shall remind staff members about the date, time, and location of the action-planning meeting following the assessment, and about the importance of participation in that meeting. Furthermore, s/he shall remind those facility representatives whose participation is expected of the need to attend. The team leader shall also remind all present about the assessment report writing process and timeline.

#### **2.4. Stage Four: Action Planning Based on Assessment Findings**

Stage Four, which involves organizing and conducting a separate session to develop an action plan (see Annex 13 for a sample plan), lasts two days on average. This session is held on a separate day following completion of the CLASS assessment. If several facilities are assessed in the same region, their action-planning sessions can be combined, by having each facility's representatives work together in small groups.

The director of the primary facility shall be responsible for organization of the action planning session; the review team leader will be responsible for facilitating the session. The facility may seek organizational and methodological assistance for the session from the UCSDDC.

During the action-planning session, it is necessary to:

- Discuss all areas identified for improvement agreed upon with facility administration.
- For each area identified for improvement, propose steps and/or actions that will enable strengthening capacity and improving activities at the facility.

- Appoint persons/organizations who will take responsibility for improving activities at the facility.
- Plan and agree on the timeframe necessary for implementation of the planned steps.
- Identify and discuss all opportunities to use available local resources that may be directed toward implementing the planned steps.
- Identify any additional technical assistance needs or resources for completing each step of the action plan.

The action planning session should include the following participants:

- Participating facility representatives. All experts responsible for the activity areas assessed shall participate in the planning session.
- CLASS review team members.
- Representatives of the local state administration (health care department).
- Representatives of other organizations that may provide technical or other types of assistance for strengthening capacity and improving quality of services (e.g., NGOs, charity funds, international charity funds, charity organizations, international charity organizations, religious charity organizations).

Session participants may vary depending on the level of the facility and scope of the assessment.

The action planning session should result in a comprehensive, feasible action plan addressing the areas for improvement identified in the CLASS assessment. Action plans usually have a timeframe of 12 or 18 months, depending on the specific situation at each CLASS-reviewed facility or organization. The action plan shall be signed by the director of the facility, the review team leader, and any other persons responsible for implementation of the planned actions. The original plan shall be held by the director of the facility. The review team leader shall keep a copy of the signed plan, and distribute copies to all persons identified as responsible for implementation of particular actions. Copies of the plan may also be sent to other stakeholders.

The director of the facility, along with those persons designated in the plan (subject to their consent), shall be responsible for implementation of the action plan.

After action planning, the facility director shall submit reports to the UCSDDC every six months during the period covered by the plan. This will allow the UCSDDC to track successes and needs, and provide support for implementation of the designated actions. The following shall be indicated by the director:

- Success and timeliness of the implemented actions.
- Delays encountered while implementing the actions, and their reasons.
- Problems and obstacles encountered while implementing the actions.
- Failure to implement actions, and the possible reasons for that failure.
- Changes in the quality of services being provided, and the activity areas that were improved based on the action plan.

The report shall be prepared using the action planning form, with additional columns – “Documentation of Achievements” and “Comment on Challenges” – added to reflect results achieved and obstacles encountered. A copy of the report shall be provided to the UCSDDC and other stakeholders.

## **2.5. Stage Five: Preparation of the Assessment Report**

Stage Five depends on the number of participating facilities, and the level of detail and depth of the assessment. This stage may last from four to six weeks.

During Stage Five, reviewers shall:

- Itemize and concretize, if necessary, all observations and findings obtained during the assessment process.
- Prepare reports (each reviewer preparing a report on his/her assessment area), and submit them to the review team leader.

Upon request, facility specialists shall provide clarifications and additional information to the reviewers for review and aggregation.

The review team leader shall prepare a draft report on the assessment findings, and provide copies of the report to the directors of the participating facilities, as well

as to all reviewers, for comments and feedback. The review team leader shall adjust the report as needed based on comments and feedback from the facilities, and then send the revised report to the CLASS national coordinator in Ukraine for consideration (when appropriate). The review team leader shall prepare two copies of the final report for signing by all review team members, then send the review team's copy to the national coordinator, and the original to the director of the participating facility. (See Annex 14 for a sample CLASS report.)

After assessments of several facilities of similar type have been completed, the UCSDDC may initiate regional and national work sessions, inviting the directors of the facilities assessed, review team members, and representatives of other stakeholders to participate. Common areas for improvement found at multiple facilities shall be discussed, and strengths identified. Specialists at the regional and national level shall present their experiences in addressing the areas for improvement.

## **2.6. Stage Six: Initiating a Continuous Quality Improvement Cycle**

The time and effort required for Stage Six—the final stage—depends on whether or not the facility already has a continuous quality improvement (CQI) system in place, and whether or not the staff possess knowledge and skills on CQI principles and implementation processes.

If the facility does not have a CQI system in place, and CQI is a new concept to staff, then this stage begins with training, followed by formation of a facility CQI team, and development/adoption of standard operating procedures (SOPs). Once the team is formed and SOPs are in place, or when facilities have functioning CQI systems, the team begins its cycle, which includes:

- Identifying the priority indicators that facility management and staff want to improve.
- Conducting a root-cause analysis to define potential targets, aims, and indicators for intervention.
- Agreeing on priority solutions for further piloting.

- Creating groups, teams, or other frameworks for implementation of selected approaches through common efforts.
- Implementing the solutions.
- Measuring the effects of changes made.
- Adjusting the selected solutions according to the measured results.

The CQI cycle shall be repeated until the set goals and objectives are reached. New indicators of success shall be identified for each new cycle, and successes and efficient approaches achieved documented for further institutionalization and rollout at other facilities and regions, and on the national level.

### **SECTION 3. EXPECTED BENEFITS OF PARTICIPATING IN A CIASS ASSESSMENT**

The anticipated benefits of using the CIASS technique for organizations and health care facilities, as well as for their administration and employees, include:

- The opportunity to experience a qualitative assessment by independent expert reviewers based on international standards.
- A focus on the achievements and successes of the organization/facility, which can strengthen employee motivation.
- Active simultaneous involvement of facility employees and management, not only in detection of areas for improvement and need, but also in joint identification of ways to improve activities and meet current/future needs.
- The CIASS assessment's role as a positive platform for mentorship and sharing experiences with national reviewers from diverse health care facilities in various regions of Ukraine.
- Obtaining sound, evidence-based assessment findings that may be successfully used for development of strategic and working action plans, as well as for raising additional financing from budget and off-budget sources and donors, including additional technical assistance.

In addition, the proposed universal tool is especially relevant in a period when the health care system is being reformed, cost-effective solutions are being sought, the patient rights movement is building, and requirements for certification of health care facilities are mounting with regard to the quality of provided clinical and social services.

Since January 2014, requirements for achieving quality health care services and quality management systems at health care facilities have been elevated. It is therefore desirable to conduct the proposed assessment and obtain CIASS findings prior to commencement of state accreditation of a health care facility for qualification

in a higher category. This is particularly important for secondary and tertiary care institutions that are about to pursue compulsory certification for the national standard DSTU ISO 9000, as well as DSTU ISO 9001, on the presence and effectiveness of a quality management system.

## CONCLUSIONS

Carrying out an assessment using the CLASS technique is recommended when:

- Facility management aspires to improve the quality of services being provided by the facility, and/or is willing to start a CQI process for those services.
- The facility has experience implementing successful, efficient activities, and its experience can be replicated at other institutions.
- The facility has problems, but its personnel lack the qualifications to identify and overcome them.
- Facility management is willing to receive recommendations for efficient functioning of the facility.
- Facility management aspires to become involved in the process of implementing the CLASS technique in Ukraine.

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## Annex 1. Administrative Module

### INTRODUCTION

The Administrative Module of the CIASS tool is a guide for assessing the completeness and quality of organization, institution, or facility management of clinical and non-clinical services provided at facilities under programs financed by state and local budgets, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and other organizations. This module is divided into six sections:

1. Governance of the Health Care Facility
2. Organizational Structure of the Health Care Facility
3. Organizational Sustainability of the Health Care Facility
4. Human Resources of the Health Care Facility
5. Organizational Management Information System
6. HCF Monitoring Activity (Regional AIDS Centers)

Each section begins with a list of core activity areas (competencies) with regard to management of the facility, based on best practices, including international practices. This list is followed by a series of questions that can be used in discussions with representatives of the facility. Verification criteria for the core activity areas and questions are provided, along with space for making notes.

The tool content is structured on the assumption that there will be at least six hours available to reviewers at each site. When time is limited, CIASS reviewers should focus on the Rapid Visit questions in each of the first five sections.

Some questions in the Section “Governance of Health Care Institution” apply to Regional Centers for Prevention and Fighting AIDS (regional AIDS centers); others apply to City Centers for Prevention and Fighting AIDS (city AIDS centers) and other lower-level health care facilities (HCFs) (e.g., ART sites, Dovira/trust rooms). In these cases, a decision will be made by the lead CIASS reviewer regarding the sections and list of questions to be applied. This decision will be made after studying information about the preliminary structure of the HCF, and statistical or other types of information regarding the HCF’s reported operations.

KEY:

Rapid visit items: (RV); Extended visit items: (EV); Partner visit items: (LP)

## Section 1: GOVERNANCE OF THE HEALTH CARE FACILITY

### Core activity areas (competencies) in the sphere of HCF management

- HCF has a well-formed, clearly defined administrative composition that provides effective supervision and coordination of work within the scope of implementation of (state and grant) programs and clinical services. (RV)
- HCF administration is governed by relevant documents. (RV)
- HCF has approved documents that specify qualifications of administration staff, as well as approved procedures for hiring and firing. (RV)
- HCF has approved documents that govern information support of administration activity, and the flow of different types of information within the facility. (RV)
- Organization of management at HCF complies with all relevant accreditation and legislative requirements. (LP)
- HCF has sufficient competent staff, including staff that conducts financial management at the facility.
- HCF management personnel with relevant authority to make decisions regarding finding additional financing for its activities in the diagnosis, prevention, and treatment of HIV.

### Questions

- Which documents define principles and procedures of HCF administrative activity? How often are these documents updated? (RV)
- What is the regularity and effectiveness of HCF administration's analysis of information (statistical, reporting, and other types of information) regarding the current state of HCF activity, including fulfillment of programs and provision of clinical services? (RV)
- Are all accreditation and licensing requirements regarding organization of facility management and staffing observed? (EV)
- How often are meetings of HCF administration and management personnel conducted with regard to analysis of information that describes the state of HCF activity, fulfillment of program activities, and provision of clinical services? (EV)
- What number and percentage of administrative personnel of HCF have the appropriate professional skills (including training in organization and management in the health care sector)?
- Who analyzes HCF financial activity? How often? Are these issues considered at administrative meetings? Are HCF employees knowledgeable about financial aspects of HCF activity?

|        | <b>Performance Criteria</b>  | <b>Verification Information</b>  | <b>Comments</b> |
|--------|--|--|-----------------|
| 1.     | HCF registration and licensing documents are current and meet legal requirements.  | <ul style="list-style-type: none"> <li>• The HCF’s clinical practice license is current.</li> <li>• HCF meets national requirements for accreditation; this is confirmed by up-to-date documentation.</li> <li>• Licenses and accreditation certificates include all types of medical care provided at the HCF.</li> </ul>   |                 |
| 2.     | HCF management functions and responsibilities are defined and approved.  | <p><b>The following is defined in the documents:</b></p> <ul style="list-style-type: none"> <li>• Structure, rights, authority, and roles of management personnel within HCF administration.</li> <li>• Duties and responsibilities of the administrative personnel of HCF.</li> <li>• Procedures for meetings of HCF administration. Minutes of the meetings and elaborated instructions are available for review.</li> </ul>   |                 |
| 3.     | Documentation of administrative activity.  | <ul style="list-style-type: none"> <li>• Agenda of meetings.</li> <li>• Information about results of fulfillment of instructions discussed at previous meetings (if necessary).</li> <li>• Matters of HCF financial reporting.</li> <li>• Reporting that describes current state of HCF activity, fulfillment of programs, and provision of clinical services.</li> <li>• Registration of people present at meetings.</li> <li>• Instructions discussed and decisions made</li> </ul>  |                 |
| 4.     | Administration   | <ul style="list-style-type: none"> <li>• Mandates and provides (if necessary) that employees sign confidentiality statements.</li> <li>• Conducts periodical assessment of current HCF activity regarding fulfillment of programs and securing provision of medical care.</li> <li>• Mandates and provides for constant improvement of employees’ professional skills.</li> <li>• Carries out activities for staff to observe by-laws.</li> <li>• Has access to legal counseling–i.e., the HCF staff roster includes an attorney, and this position is occupied.</li> </ul>  |                 |
| 5.     | Administration is informed, in particular about fulfillment of programs and provision of medical care, through the following:                  | <ul style="list-style-type: none"> <li>• Reports presented by employees and/or heads of HCF departments at administrative meetings.</li> <li>• Employees and/or department heads provide information in the form of reports and/or internal memos.</li> <li>• Written and/or verbal (oral) reports, upon request of administration, regarding implementation of sector programs and the results of provision of medical care.</li> <li>• Employees and/or heads of departments provide analytical documents based on data from statistical reports, results of fulfillment of sector programs, and results of provision of clinical services.</li> </ul> |                 |
| 6.     | An annual assessment of the effectiveness and quality of medical care in general, and under individual departments in particular, is provided. |  |                 |
| Notes: |  |  |                 |

## Section 2: ORGANIZATIONAL STRUCTURE OF THE HEALTH CARE FACILITY

### Core activity areas (competencies) in the sphere of HCF management

- HCF has an efficient management structure that shows lines of responsibility for each structural subdivision, and is presented in an organogram. (RV)
- HCF has efficient channels for internal communication among administrative staff, heads of structural subdivisions, and facility employees, in accordance with their respective functions. (RV)
- HCF operating procedures are approved by management, and communicated to employees.
- HCF has a well-organized, efficient system for the exchange of internal and external information, enabling timely decision-making by administration and heads of structural subdivisions. (EV)
- HCF has a clearly defined algorithm of actions or action plan for cases of emergency (e.g., loss of power, disruption of water supply). (EV)

### Questions

- Does an organogram reflect the system of subordination and communication among administration, heads of structural subdivisions, and other staff employees? (RV)
- How is information communicated from management personnel to heads of structural subdivisions and staff employees (e.g., regarding changes in the institutional composition of HCF, principles of work, other important organizational decisions)? Are these processes effective? Do they occur in a timely manner? (RV)
- Do employees have an opportunity to receive from administration all types of information (e.g., scientific, instructive, statistical) on any issues/needs? (RV)
- How does administration initiate consideration and discussion of problems regarding HCF activity? What documents confirm that decisions were made with regard to resolving important issues raised for discussion with heads of structural subdivisions and/or staff employees? (EV)
- Are staff employees aware of an algorithm of actions in case emergency situations occur in the workplace? If so, for which situations? (EV)

|    | <b>Performance Criteria</b>  | <b>Verification Information</b>   | <b>Comments</b> |
|----|--|---|-----------------|
| 1. | The organogram reflects current lines of authority.  | <ul style="list-style-type: none"> <li>• The facility has an organogram.</li> <li>• The organogram fully labels structural subdivisions, staff positions, distribution of duties, and terms of reference with regard to fulfillment of programs and sufficient staff to provide clinical services.</li> </ul> |                 |
| 2. | Lines of authority and terms of reference are appropriate for staff positions.                         | <ul style="list-style-type: none"> <li>• Job descriptions fully list the levels of competence required, and the scope of necessary services provided, for each staff position.</li> </ul>   |                 |
| 3. | Lines of authority and terms of reference are appropriate for managerial and administrative positions. | <ul style="list-style-type: none"> <li>• Job descriptions fully list the levels of competence required, and the scope of necessary services provided, for heads of structural subdivisions and management personnel.</li> </ul>   |                 |

|    |  |   |  |
|----|--|---|--|
| 4. | Frequency and efficiency of information exchange between administration and employees.   | • Administration is occasionally present at meetings of structural subdivisions.  |  |
|    |  | • Meetings of administration are conducted regularly (at least twice a year); heads of structural subdivisions and employees are present at these meetings. |  |
|    |  | • General meetings of employees are conducted, with participation of heads of structural subdivisions and administration.                                   |  |
|    |  | • Other   |  |
| 5. | Meetings among administration and heads of structural subdivisions.  | • Meetings are held/not held  |  |
|    |  | • Meeting frequency:  |  |
|    |  | • How are meetings documented?  |  |
| 6. | <b>Staff Understanding of HCF Organogram:</b><br><i>(In the process of conducting the assessment, the reviewer refers to the HCF organogram to check how well staff employees understand it—e.g., have they ever seen it? Where are they on the organogram? In their view, is the organogram clear, complete, and informative?).</i> |   |  |

| Employee Position | Employee 1 | Employee 2 | Employee 3 | Employee 4 |
|-------------------|------------|------------|------------|------------|
| A                 |            |            |            |            |
| B                 |            |            |            |            |
| C                 |            |            |            |            |
| D                 |            |            |            |            |
| E                 |            |            |            |            |
|                   |            |            |            |            |
| Notes             |            |            |            |            |

### Section 3: ORGANIZATIONAL SUSTAINABILITY OF THE HEALTH CARE FACILITY

#### Core activity areas (competencies) in the sphere of management of a medical facility

- There is a strategic planning process and written plan in place for HCF that is reviewed and modified at appropriate intervals, as needed.
- HCF has both short- and long-term plans for recruitment and retention of staff, particularly for management-level positions.
- HCF has a process to keep abreast of available resources to improve organization capacity, maintain existing service delivery, and seek and obtain support from diverse funding streams.

#### Questions

##### *Strategic Planning*

- What is the strategic planning process for the HCF? Who participates in the process? How often is the process implemented? What products result from the process? (RV)
- What short- and long-term plans does HCF have to provide and retain the required number of staff employees?
- How does HCF carry out planning of activities to provide sustainability, corresponding volumes, and quality of clinical services as the number of patients served steadily increases?
- How has HCF been able to show in the last year (sustainability planning) that management personnel and general staff will be able to maintain quality as they handle additional volumes of work, and accommodate increased responsibilities, with regard to implementation of program activities?

### **Fundraising**

- How does HCF plan to sustain current levels of service and staffing over the next three years? The next five years? The next ten years? (EV)
- What is the ability of HCF as a grantee to write its own grant proposals? Consider: Did HCF complete development of an independent proposal, or did it assign preparation of a grant proposal to a trusted NGO? Has HCF submitted acceptable applications? Has it won actual awards? (LP)

### **Capacity Building**

- How does HCF ensure appropriate professional skill levels among management personnel, clinical workers, and staff and non-staff non-clinical workers?
- Does HCF management personnel have required levels of knowledge and competence for providing effective HCF management as a grantee?
- How does HCF plan to ensure the necessary levels of knowledge and competence of management personnel for effective management of HCF as a grantee?

### **Strategic Planning**

|    | <b>Performance Criteria</b>   | <b>Verification Information</b>   |     |    | <b>Comments</b> |
|----|---|---|-----|----|-----------------|
| 1. | There is a strategic planning process in place.   | <ul style="list-style-type: none"> <li>• Minutes/recording of planning meeting(s).</li> <li>• Written strategic plan with specific dates.</li> <li>• Status report on plan content.</li> </ul>  |     |    |                 |
| 2. | Employees involved in the strategic planning process.   | <ul style="list-style-type: none"> <li>• HCF leadership</li> <li>• Heads of HCF structural subdivisions</li> <li>• Staff clinical workers</li> <li>• Representatives of patient organizations</li> <li>• Other interested parties (if necessary)</li> </ul> | Yes | No |                 |
| 3. | There is a plan or process in place to maintain proper professional skills among HCF employees.   |   |     |    |                 |
| 4. | HCF has a plan in place allowing the facility to sustain or grow the current level or quality of service delivery.                            |   |     |    |                 |
| 5. | HCF has a plan in place allowing the facility to maintain or acquire the ability to provide oversight or supervision of grant implementation. |   |     |    |                 |

### **Fundraising**

|    | <b>Performance Criteria</b>  | <b>Verification Information</b> | <b>Comments</b> |
|----|--|---------------------------------|-----------------|
| 1. | HCF has experience obtaining additional financing.   | <i>Describe</i>                 |                 |
| 2. | HCF has experience in efficient management and implementation of activity, whether as part of implementation of grant agreements or subsequent to bidding. | <i>Describe</i>                 |                 |
| 3. | HCF has a plan for obtaining additional financing for the future.  | <i>Describe</i>                 |                 |

### Capacity-building

|       | Performance Criteria   | Verification Information   | Comments |
|-------|--|--|----------|
| 1.    | There is a process in place for management to identify training and essential technical assistance needs.                              |  |          |
| 2.    | There is a process in place for management to assess capacity-building needs, and to address those needs through technical assistance. |  |          |
| 3.    | HCF has internal processes in place to assess departments (structural subdivisions) and address technical assistance needs.            |  |          |
| 4.    | HCF encourages its employees to improve their skills:  | <ul style="list-style-type: none"> <li>Employees have opportunities for on-the-job training.</li> </ul>                            |          |
|       |  | <ul style="list-style-type: none"> <li>HCF pays for employee training.</li> </ul>  |          |
|       |  | <ul style="list-style-type: none"> <li>For the training period, employees have an opportunity to take time off instead.</li> </ul> |          |
|       |  | <ul style="list-style-type: none"> <li>Employees have Internet access to help them improve their skills.</li> </ul>                |          |
|       |  | <ul style="list-style-type: none"> <li>Other</li> </ul>  |          |
| Notes |  |  |          |

## Section 4: HUMAN RESOURCES AT THE HEALTH CARE FACILITY

### Core activity areas (competencies) in the sphere of management of a medical facility

#### *Staffing & Personnel*

- Each position at HCF has a written job description; employees can clearly identify their duties. (RV)
- HCF has an approved plan in place to address needs for recruitment, training, and retention of qualified staff to support operations. (EV)
- HCF management personnel, including those responsible for financial management, are provided opportunities to improve their skills and knowledge in their specialties.

#### *Personnel Policies, Procedures & Files*

- Personnel policies and procedures contain information on employee rights and responsibilities. (RV)
- HCF leadership provides employees with opportunities to familiarize themselves with these documents. (RV)
- HCF personnel policies and procedures comply with established laws. (RV)
- HCF maintains an employee database (personnel files); employee records contain required information and documentation regarding skills and qualifications. (EV)

### Questions

#### *Staffing & Personnel*

- How does HCF ensure that established labor laws are being followed? (RV)
- How are staff (clinical and non-clinical) credentials (e.g., diplomas) verified? (RV)
- What orientation does HCF provide for new employees? How is information about an employee's resignation communicated to structural subdivisions? (RV)
- What short- and long-term plans does HCF have in place to recruit and retain staff? (EV)

**Personnel Policies, Procedures, & Files**

- Has HCF developed work performance criteria for administration, heads of structural subdivisions, and clinical and non-clinical staff?
- How often are performance evaluations given? What criteria are used? (RV)
- How is information regarding staff schedules developed, reviewed, updated, and communicated to employees? Who participates in these processes? (EV)
- Who reviews and updates job descriptions? How often? (EV)
- What documents are kept in personnel files? Who maintains this information? Who can access the documents? (EV)
- Does HCF exercise any control over the health of its employees, both clinical and non-clinical?

**Staffing & Personnel**

|    | <b>Performance Criteria</b>  | <b>Verification Information</b>  | <b>Comments</b> |
|----|--|--|-----------------|
| 1. | HCF has current internal regulations, duly approved by the head of HCF.  | <ul style="list-style-type: none"> <li>• There are written, duly approved internal regulations.</li> <li>• All employees are familiar with internal regulations.</li> <li>• Internal regulations contain information for staff about their rights and responsibilities.</li> <li>• The internal regulations of HCF comply with national requirements regarding working hours of medical sphere specialists.</li> </ul> |                 |
| 2. | There are job descriptions available for all HCF positions.  | <ul style="list-style-type: none"> <li>• All positions have written job/position descriptions. If not, an explanation is required.</li> <li>• Employees receive copies of their job/position descriptions.</li> </ul>  |                 |
| 3. | HCF employees are able to fully identify their duties consistent with their job descriptions. <i>(In the process of assessment it is necessary to interview both clinical and non-clinical staff.)</i> | <ul style="list-style-type: none"> <li>• Position: _____</li> </ul>  |                 |
| 4. | There are appropriate written agreements for non-staff and contracted workers (e.g., social workers, volunteers) to define their duties and methods of remuneration.                                   | <ul style="list-style-type: none"> <li>• Consultant agreements.</li> <li>• Contractual agreements.</li> </ul>  |                 |
| 5. | HCF has a strategy to recruit and retain staff.  | <i>Describe</i>  |                 |

### Personnel Policies & Procedures

|   | Performance Criteria   | Verification Information   | Comments |
|---|--|--|----------|
| 1.  | The following information is outlined in the internal regulations governing the process of working with staff: | • Personnel office contact details.  |          |
|   |  | • Employment status.   |          |
|   |  | • Work hours or timeframes.  |          |
|   |  | • Benefit options/bonuses/severance pay.   |          |
|   |  | • Orientation procedures for HCF/department (structural subdivision).  |          |
|   |  | • Standards of conduct.  |          |
|   |  | • Probation period and performance evaluation.   |          |
|   |  | • Order of subordination in case members of the same family work in HCF (in case this is stipulated by current legislation).                             |          |
|   |  | • Disciplinary actions and appeal procedures.  |          |
|   |  | • Procedure for consideration of employee complaints.  |          |
|   |  | • Policy defining conflicts of interest.   |          |
|   |  | • Observance of subordination.   |          |
|   |  | • Observance of confidentiality.   |          |
|   |  | • Employee skill verification vs. job requirements.  |          |
| • Employee licenses and certifications (when required). |  |  |          |
| • Continuing education for employees.                   |  |  |          |
| 2.  | Employee health policies adequately address:   | • Hepatitis B vaccinations.  |          |
|   |  | • Recurrent, regular dispensary examination of designated groups of employees.   |          |
|   |  | • Procedures to be followed in case of an emergency with risk of contracting HIV comply with the current regulatory system (current clinical protocols). |          |
|   |  | • HIV post-exposure prophylaxis (PEP) and follow-up, either directly in HCF, or by referral.   |          |
|   |  | • Providing insurance for employees in case of on-the-job contraction of HIV.  |          |
|   |  | • Other (indicate).  |          |

### Personnel Files

|    | Performance Criteria   | Comments |
|----|--|----------|
| 1. | Personnel files (personal records) are maintained in a safe, secure area.  |          |
| 2. | There are written policies specifying who may access personnel files (personal records).   |          |
| 3. | Each personnel file contains a checklist of its required content (personal records).   |          |
| 4. | Confidentially review at least one personnel file (personal record) for each category of employee (e.g., physician, nurse, counselor, registration clerk) working at HCF and engaged in providing medical care to patients with HIV: |          |

| Employee Position                                     | Employee 1 | Employee 2 | Employee 3 | Employee 4 |
|---|------------|------------|------------|------------|
| • Job duties.   |            |            |            |            |
| • Evidence that employee meets position requirements. |            |            |            |            |

|  |  |  |  |  |
|--|--|--|--|--|
| • Performance appraisals/evaluations (within the last two years).  |  |  |  |  |
| • Salary increases or decreases.   |  |  |  |  |
| • Training or continuing education.  |  |  |  |  |
| <i>Clinical staff or any staff member requiring a diploma to perform the job.</i>  |  |  |  |  |
| • Credentials of staff (diploma).  |  |  |  |  |
| • Documents confirming improvement in employee skills and qualifications, in accordance with current regulations.  |  |  |  |  |
| <i>Employee health files kept at HCF.</i>  |  |  |  |  |
| • Availability of the sanitary books of employees belonging to designated groups.  |  |  |  |  |
| • Employee medical documentation (sanitary book) contains notes on regular medical examinations.<br><i>(Look through the sanitary books of a few employees.)</i> |  |  |  |  |
| Notes  |  |  |  |  |

## **Section 5: ORGANIZATIONAL MANAGEMENT INFORMATION SYSTEM**

### **Core activity areas (competencies) in the sphere of HCF management**

#### ***Management Information System (MIS)***

- HCF has information systems in place for operations data management, including the capacity to collect, store, and retrieve operations or program data for planning, monitoring, reporting, and improving quality of services. (RV)
- There are procedures in place to verify the quality of MIS data (e.g., accuracy, completeness, and timeliness of provision of medical care). (RV)
- Management and planning processes demonstrate effective use of MIS data in decision-making. (RV)
- The MIS is able to produce reports that comply with administration requirements. (EV)
- The MIS is able to produce reports that comply with requirements of (external) funders, where applicable. (EV)

#### ***Policies & Procedures***

- HCF has policies and procedures to govern MIS use, access, maintenance, and security. (RV)
- HCF has staff with appropriate experience and training in operation and administration of information systems. (EV)
- HCF has processes to ensure that all staff employees have adequate training on data management systems related to their assigned areas. (EV)

#### ***Reporting***

- HCF is able to safely store and efficiently retrieve MIS data as required. (RV)
- HCF is able to generate reports that conform to the requirements of international partner organizations (e.g., Global Fund). (EV)

#### ***Security and access***

- HCF has adequate systems in place to enable proper implementation of policies to ensure the security of organization, employee, and patient data. (EV)

## Questions

### MIS

- What are the routine systems used to report, collect, and analyze data on patient health status, organization services, human resources, and finances? (RV)
- How does management resolve and find timely solutions to equipment, software, or data management problems? (RV)
- What system, equipment, and software training has been provided for staff? How often is software updated? (EV)
- If there are different systems for capturing data within HCF, how is information shared and compared? (EV)
- How is the information system updated to accommodate new data requirements? How are additions to the information system communicated to data collection or other staff? (EV)

### Reporting

- What reports can the available information system prepare? Are they prepared and provided in a timely manner? Are they complete? Are they sufficient to meet the needs of HCF and donors? (RV)
- What drawbacks are there collecting data via the information system? Are there systemic gaps in the system that cause delays in providing needed information and/or reports? (EV)

### Security & Access

- What security systems and processes, including antivirus and malware protection, are in place at the HCF to protect its information systems? Do they provide sufficient protection? (EV)

## Management Information System

|    | Performance Criteria                                    | Verification Information   | Comments |
|----|---|--|----------|
| 1. | HCF has designated specialists responsible for MIS.     | <ul style="list-style-type: none"> <li>• Information system specialist responsible for monitoring use of pharmaceuticals and medical devices.</li> </ul> |          |
|    |   | <ul style="list-style-type: none"> <li>• Information system specialist responsible for maintaining human resource (HR) records.</li> </ul>               |          |
|    |   | <ul style="list-style-type: none"> <li>• Information system specialist responsible for monitoring financial resources.</li> </ul>                        |          |
|    |   | <ul style="list-style-type: none"> <li>• Information system specialist responsible for monitoring provision of clinical services.</li> </ul>             |          |
|    |   | <ul style="list-style-type: none"> <li>• Other (indicate).</li> </ul>  |          |
| 2. | HCF has automated systems to capture organization data. | <ul style="list-style-type: none"> <li>• Accounting software, including payroll.</li> </ul>  |          |
|    |   | <ul style="list-style-type: none"> <li>• Automated monitoring system to track HCF inventory of pharmaceuticals and medical equipment.</li> </ul>         |          |
|    |   | <ul style="list-style-type: none"> <li>• Clinical database or electronic medical records (EMR).</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>• HR database (systems of electronic HR department).</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>• Excel spreadsheets are used as an automated system for maintaining records of HCF resources.</li> </ul>         |          |
|    |   | <ul style="list-style-type: none"> <li>• No automated system in place. (<i>Instead describe what exists.</i>)</li> </ul>                                 |          |

|    |  |  |  |
|----|--|--|--|
| 3. | Describe the information technology (IT) infrastructure and architecture.      | • Local/wide area network (LAN/WAN).   |  |
|    |  | • Standalone PCs.  |  |
|    |  | • Other (please specify).  |  |
| 4. | Management personnel perform analyses of data reports used in decision-making. | • Analysis of reporting data is presented at administration meetings, and meetings with heads of HCF structural subdivision (with participation of staff employees). |  |
|    |  | • Meeting minutes show how analytical data is used in decision-making.   |  |
|    |  | • Other.   |  |

### Policies & Procedures

|    | Performance Criteria  | Verification Information  | Comments |
|----|---|---|----------|
| 1. | MIS policies and procedures exist and are adequate.   | • Written procedures of MIS operation for each subdivision are approved by leadership.  |          |
|    |   | • Operating procedures are in place, but are not documented in writing.   |          |
|    |   | • Operating procedures are updated periodically.  |          |
|    |   | • Specific operating procedures in place, including those for data collection, maintenance, quality, and security.                                  |          |
|    |   | • HCF does not have formal MIS operating procedures.  |          |
| 2. | There are procedures in place to verify quality of data (e.g., accuracy, timeliness, and completeness). | • Data verification procedures have been developed, and are in place in every subdivision.  |          |
|    |   | • Each department has its own verification process.   |          |
|    |   | • Verification of data accuracy is performed before creating reporting documentation.   |          |
|    |   | • There are no data quality processes in place.   |          |
| 3. | Staff are aware of procedures to be used to address equipment and software/program problems.            | • These procedures are part of MIS operating procedures.  |          |
|    |   | • HCF can involve the relevant specialists to eliminate problems in operation of the information system.  |          |
|    |   | • Process of elimination (troubleshooting) to identify problems and deficiencies in operation of the information system is non-existent or unclear. |          |

## Reporting

|       | Performance Criteria  | Comments |
|-------|---|----------|
| 1.    | HCF is able to meet all data reporting requirements and requests.                                       |          |
| 2.    | Staff is able to request system updates (modifications) to accommodate new data reporting requirements. |          |
| Notes |   |          |

### Section 6: HCF MONITORING ACTIVITY (Regional AIDS Centers)

#### Core activity areas (competencies) in the sphere of management of a medical facility

- A regional or city HCF that provides on-site ART has in place work principles and policies that specify reporting requirements, and program monitoring policies and procedures. Relevant documentation is available to management specialists.
- HCF has processes in place to train program staff on monitoring guidelines, and assistance or cooperation options for regional and city HCFs that provide on-site ART.
- HCF can conduct supportive supervisory visits on a regular schedule at both regional and city facilities, as well as at NGO-operated facilities, to monitor provision of services to most-at-risk patients (MARPs) and HIV-positive patients.

#### Questions

- Has a written plan been developed for conducting monitoring visits? Has the plan been duly approved at the regional level?
- Has the HCF assigned specialists to conduct monitoring visits, including clinical audits, to assess quality of medical care provided to HIV-positive patients?
- Has a clear mechanism been developed for regional and city HCFs that provide ART, whether on site or through partner NGOs, to file reports regarding provision of services?
- Are all interested parties provided with documents that explain the principles and procedures involved in monitoring provision of clinical and non-clinical services to MARPs and HIV-positive patients? Are these documents reviewed, updated, and duly approved?
- What is the process for conducting monitoring visits?
- Are visits planned and coordinated in advance? How often are they conducted?
- What programs or service areas are covered during these visits? How are visits coordinated among different regional and city HCFs that provide clinical services to HIV-positive patients on site and/or through partner NGOs (if required)?
- What advance notice of monitoring visits is provided?
- What feedback or findings from these facilities are shared after the visit?
- How are findings addressed? How are proposals for improvement made during a visit managed?
- Are facilities given the opportunity to remedy operational deficiencies identified in the findings?
- How are follow-up visits conducted, when needed, to check on whether or not deficiencies have been addressed?
- How are results of visits to these facilities documented?

|    | Performance Criteria  | Verification Information   | Comments |
|----|---|--|----------|
| 1. | Reporting by regional and city HCFs that provide clinical services to | <ul style="list-style-type: none"> <li>• Regular, on-time submission of reports enables compilation of regional reports in a timely manner.</li> </ul>         |          |
|    |   | <ul style="list-style-type: none"> <li>• Reports are provided according to requirements, and in approved formats, and contain detailed information.</li> </ul> |          |

|  |  |   |  |
|--|--|---|--|
|  | HIV-positive patients on site.   | <ul style="list-style-type: none"> <li>Reporting forms adequately reflect results of program activities implemented and medical care provided.</li> </ul> |  |
| 2.   | Procedure (plan) for monitoring activities of regional and city HCFs that provide clinical services to HIV-positive patients on site.                | <ul style="list-style-type: none"> <li>A written procedure (plan) for conducting visits is in place.</li> </ul>   |  |
| <ul style="list-style-type: none"> <li>A procedure (plan) for conducting visits has been approved at the regional level.</li> </ul>  |  |   |  |
| <ul style="list-style-type: none"> <li>A procedure (plan) for conducting visits is reviewed periodically (at least once a year).</li> </ul>  |  |   |  |
| <ul style="list-style-type: none"> <li>A procedure (plan) for conducting visits has been disseminated to HCF management.</li> </ul>  |  |   |  |
| 3.   | Monitoring visits to regional and city HCFs that provide clinical services to HIV-positive patients on site.   | <ul style="list-style-type: none"> <li>There are specialists assigned to conduct monitoring visits</li> </ul>   |  |
| <ul style="list-style-type: none"> <li>A program for conducting monitoring visits has been developed and disseminated to the specialists responsible for making the visits.</li> </ul>   |  |   |  |
| <ul style="list-style-type: none"> <li>Visits are conducted at least once every two years at HCFs in the region, as specified by the plan.</li> </ul>  |  |   |  |
| <ul style="list-style-type: none"> <li>Visits are documented and certified (through signatures) by the specialists conducting them, and by the heads of HCFs where assessments are performed.</li> </ul>   |  |   |  |
| <ul style="list-style-type: none"> <li>Recommendations regarding improvements to work procedures are passed along to the heads of HCFs where assessments are performed.</li> </ul>   |  |   |  |
| 4.   | Travel.  | <ul style="list-style-type: none"> <li>Requests for travel are duly approved according to established legislation.</li> </ul>                             |  |
| <ul style="list-style-type: none"> <li>A mechanism is in place to provide for compensation of travel expenses incurred.</li> </ul>   |  |   |  |
| <ul style="list-style-type: none"> <li>A mechanism is in place to provide for compensation of travel expenses based on preliminary estimates.</li> </ul>   |  |   |  |
| <ul style="list-style-type: none"> <li>A mechanism is in place to provide payment of per diem for travel expenses.</li> </ul>  |  |   |  |
| <ul style="list-style-type: none"> <li>A mechanism for compensation of expenses provides for compensation of employee travel expenses during a relevant time period, until the next time the employee needs to travel, as approved by their supervisor.</li> </ul> |  |   |  |
| 5.   | Supervisory and technical assistance visits to regional and city HCFs that provide clinical services to HIV-positive patients on site are performed. |   |  |
| Notes  |  |   |  |

## **Annex 2. Financial Module**

### **INTRODUCTION**

The Financial Module of the CLASS tool is a guide for assessing financial systems at a facility or organization. This module is divided into nine sections:

- Financial Management and Oversight
- Principles of Operation and Financing Procedure
- Budget Management
- Financial Management Information Systems
- Accounting Systems–Payroll
- Accounting Systems–Documentation, Internal Controls, and Cash
- Procurement, Purchasing, Inventory
- Financial Program Monitoring and Oversight
- Grants and Contract Management (Organization That Is or Plans to Become a Grantor)

All nine sections, including Grants and Contract Management, are for use at both medical and non-medical facilities. The Grants and Contract Management section is relevant for both budget-supported and private (non-governmental) institutions that plan or carry out their activity as grantees.

Each section begins with a list of core activity areas (competencies) that have been developed based on best practices established by international organizations. This list is followed by a series of questions that can be used in discussions with representatives of the facility. Verification criteria for the core activity areas and questions are provided, along with space for making notes.

**KEY:**

Rapid visit items: (RV); Extended visit items: (EV); Partner visit items: (LP)

**Section 1: FINANCIAL MANAGEMENT AND OVERSIGHT**

**Core Activity Areas (Competencies)**

- The number of staff positions and the qualifications of employees working at the HCF are sufficient for financial management of the facility and its HIV programs.
- HCF heads with appropriate authority make decisions on budget formulation, expenditure of funds (spending), and grant seeking.
- HCF creates conditions that allow for ongoing education of staff employees, and ensure training of financial department personnel.
- Financial specialists possess the skills and expertise necessary to manage the organization and its grants.
- The organization has procedure in place to implement, assess, and improve the quality of its financial systems and processes.

**Questions**

- Please list all staff positions associated with finance, indicating actual numbers of staff and vacancies. Do you specify education, qualifications, and duties required for staff positions?
- Are the professional qualifications and experience of each key employee who works in financial management appropriate for his/her position? Do they satisfy the needs of the facility? (RV)
- How are HCF funding and spending decisions made? Who makes those decisions? (EV)
- Describe the financial performance and qualification-improvement initiatives implemented within the organization. Who is responsible for this process? (EV)

|    | <b>Performance Criteria</b>   | <b>Verification Information</b>   | <b>Comments</b> |
|----|---|---|-----------------|
| 1. | Beyond normal state or local sources of budget, designated financial staff provide financial management within the framework of a grant.                            | <ul style="list-style-type: none"> <li>• Financial Manager.</li> <li>• Chief Accountant.</li> <li>• Chief Economist.</li> <li>• Economist.</li> <li>• Accountant.</li> <li>• Cashier.</li> <li>• Head of Procurement.</li> <li>• Procurement Specialist.</li> <li>• Other employees.</li> </ul>   |                 |
| 2. | HCF applies separate procedures for recruitment/retention of qualified financial staff and evaluation of financial staffing levels within the framework of a grant. | <ul style="list-style-type: none"> <li>• Processes exist for recruiting staff and evaluating the qualifications and experience of individuals hired.</li> <li>• Job descriptions specify levels of experience and education for employees occupying all positions.</li> <li>• Management personnel or program specialists who work under a grant program have input in hiring decisions.</li> </ul> |                 |

|       |   |  |  |
|-------|---|--|--|
|       |   | <ul style="list-style-type: none"> <li>• Staff employees are properly cross-trained; HCF provides opportunities for development.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Staffing levels are sufficient to perform grant management work.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• HCF has a staff retention plan in place.</li> </ul>   |  |
| 3.    | Decision-making process regarding financing HIV programs that are funded from different sources (state/local budgets, grants).                              | <ul style="list-style-type: none"> <li>• HCF management makes decisions directly on the regional level, in terms of allocating funds from local budget for HIV programs, and/or opportunities to receive grants.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• HCF management participates in decision-making processes on the regional level, in terms of allocating funds from local budget for HIV programs, and/or opportunities to receive grants.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Decisions regarding allocation of funds from local budget for HIV programs, and/or opportunities to receive grants, are made without participation of HCF management.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• The procedure of making decisions regarding allocation of funds for HIV programs, and/or obtaining grants, is not clear.</li> </ul>   |  |
| 4.    | HCF management makes decisions regarding how funds from different sources are allocated to cover HIV program expenditures.                                  | <ul style="list-style-type: none"> <li>• In order to avoid duplicate funding, management analyzes program expenditures; based on the results of this analysis, it determines how funds from different sources are allocated to cover those expenses.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• In order to avoid duplicate funding, management participates in the process of analyzing program expenditures, which is directly carried out by specialists in the financial department; based on the results of this analysis, it participates in the process of determining how funds are allocated to cover those expenses.</li> </ul> |  |
|       |   | <ul style="list-style-type: none"> <li>• Analysis of program expenditures, and decisions regarding allocation of funds to cover those expenses, are made by specialists in the financial department without management participation.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• The mechanism for determining allocation of funds from different sources to cover HIV program expenditures is not clear.</li> </ul>   |  |
| 5.    | Financial staff have access to training or opportunities to improve their professional skills:  | <ul style="list-style-type: none"> <li>• Quarterly.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Twice a year.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Annually.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• As needed.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• No training opportunities are provided.</li> </ul>  |  |
| 6.    | HCF has a system in place to assess the work quality and efficiency of financial staff, including those involved in financial management of grant programs. |  |  |
| Notes |   |  |  |

## Section 2: PRINCIPLES OF OPERATION AND FINANCING PROCEDURE

### Core Activity Areas (Competencies)

- The organization has a procedure in place for tracking expenses; the procedure applies to the entire organization, and is constantly observed by staff whose work concerns financial responsibility and liability.
- The procedure covers:
  - Budgeted expenses (under state or local budgets).
  - Accounting.
  - Salaries, including remuneration under grant agreements.
  - Procurement.
  - Travel expenses.
  - Accounts payable.
  - Accounts receivable, including receivables under agreements and contracts.

### Questions

- Have persons been designated to develop procedure for tracking operations, and assume responsibility for its observance?
- Has an algorithm been defined for making changes to procedure, and for communicating those changes to all designated specialists in HCF?
- Are all areas of financial activity covered by the procedure?
- Has a mechanism been developed and implemented for assessing how well responsible specialists at the HCF are following procedure?

|    | Performance Criteria   | Verification Information  | Comments |
|----|--|---|----------|
| 1. | The organization has a formal procedure in place for tracking financial operations.  | • The organization has a formal procedure in place; the governing documents are available for reference by financial management personnel.  |          |
|    |  | • Designated employees are familiar with procedures for tracking financial operations, but the organization does not have a formal procedure in place.  |          |
|    |  | • All financial processes have been put in writing, but the organization does not have in place a formal procedure for tracking financial operations as part of its activity.   |          |
|    |  | • Some financial processes have been put in writing.  |          |
| 2. | A procedure for tracking financial operations has been approved by HCF management.   | • A procedure for tracking financial operations has been approved and adopted by the organization.  |          |
|    |  | • Such approval has been recorded in the minutes of HCF leadership meetings.  |          |
|    |  | • A procedure for tracking financial operations has not been approved and adopted by the organization.  |          |
| 3. | A procedure for tracking financial operations has been provided to HCF directors, grant coordinators, and designated specialists within the HCF. | • The procedure is communicated to HCF managers, grant coordinators, and designated specialists within the HCF at the beginning of the fiscal year.   |          |
|    |  | • The procedure is communicated to HCF directors and grant coordinators at the beginning of the fiscal year; the procedure is later communicated to designated specialists within the HCF during meetings of the facility's subdivisions. |          |

|       |  |  |  |
|-------|--|--|--|
|       |  | <ul style="list-style-type: none"> <li>Designated specialists within the HCF receive copies of the procedure via email or letter from HCF coordinators or management.</li> </ul>   |  |
|       |  | <ul style="list-style-type: none"> <li>The procedure for tracking financial operations is not communicated to designated specialists within the HCF.</li> </ul>  |  |
| 4.    | The procedure for tracking financial operations includes adequate provision for implementing procurement procedures. | <ul style="list-style-type: none"> <li>Procurement procedures have been approved and implemented by HCF management.</li> <li>Procurement procedures are comprehensive, and address specific processes, from placement of orders to receipt and payment of goods and services.</li> <li>Procurement procedures adopted by HCF prohibit arranging the purchase, lease, or ordering, or recommending the purchase or ordering of any goods, facilities, or services, for personal benefit.</li> <li>Procurement procedures clearly define purchasing quotas based on cost, delivery terms, suppliers, etc.</li> <li>Procurement procedures define the budgeting process, financial office contacts, the organization's fiscal year, signature authority for purchase order approvals, etc.</li> </ul> |  |
| 5.    | Policies and procedures are being followed in accordance with current legislation.                                   | <ul style="list-style-type: none"> <li>Procurement procedures.</li> <li>Debt collection procedures.</li> <li>Salary accounting and remuneration procedures.</li> <li>Accounts payable policies.</li> </ul>   |  |
| 6.    | Adequate procedures are in place to address travel expenses.   | <ul style="list-style-type: none"> <li>Advance approval of travel plans.</li> <li>A mechanism is in place to pay out travel expenses in advance.</li> <li>The procedures clearly define reimbursement of expenses based on per diem rates, versus reimbursement based on actual incurred expenses.</li> <li>Submission of travel expense reports and travel settlement process.</li> <li>The procedure clearly specifies those expenses requiring receipts.</li> </ul>   |  |
| Notes |  |  |  |

### Section 3: BUDGET MANAGEMENT

#### Core Activity Areas (Competencies)

- The organization's budget complies with legal norms and requirements, and appropriately reflects the organization's activity under different directives and funding sources.
- The organization receives funding from different sources.
- The organization has a detailed budget development and approval process consistent with all requirements of legislation (or a grantor); approval is compliant with standard practices.
- Salaries (remuneration) and employee benefits are provided at levels consistent with current labor laws and sector standards, and take into account employee qualifications, workloads, and levels of responsibility.
- The organization analyzes the line-item budget, and performs operation management based on

that budget.

- The proposed budget for grant activity reflects a relevant approved work plan based on expenditures.
- Comparisons of budgeted expenses with actual expenditures are performed monthly or quarterly, and causes of variances explored.

### Questions

- Does the organization’s budget request and line-item budget (the organization’s budget) take into account current laws, as well as sources of funding and the needs of its structural subdivisions (grantor requirements)?  
For example:
  - HIV program budget (including funds from all sources).
  - Program budget separated out by funding sources, including grants.
  - Consolidated budget for the HCF.
  - Budgets for each of the structural subdivisions.
- Does the budget reflect the activity of the organization as a whole?
- What mechanisms are in place to manage budgets under different funding sources?
- What is the mechanism in place to prepare, approve, and/or revise the budget?
- Does the proposed budget meet the needs reflected in the work plan?
- Are expenditures audited for consistency of approved expenditures under the line-item budget with actual expenses? Is this done regularly? Explain the differences between budgeted and actual expenses.

|    | <b>Performance Criteria</b>   | <b>Verification Information</b>  | <b>Comments</b> |
|----|---|--|-----------------|
| 1. | The organization has in place a clear and systematic approach for management of multiple funding sources. | • There is a separate budget for each activity or funding source.  |                 |
|    |   | • Budget details and actual revenues/expenses can be displayed for any range of dates by program, both by funding source and in aggregate. |                 |
|    |   | • There is a reasonable system in place for allocating salaries and other costs to multiple budgets.                                       |                 |
|    |   | • There is a mechanism in place to ensure that there are no cost overruns or duplication of charges.                                       |                 |
| 2. | The organization’s annual budget is developed by the following person (persons):                          | • The head of the organization.  |                 |
|    |   | • The head of the organization, together with the accounting, financial, and procurement departments.                                      |                 |
|    |   | • Financial manager (chief accountant), or the organization’s chief economist.   |                 |
|    |   | • Employees of the financial, procurement, and/or accounting departments.  |                 |
|    |   | • Other employees.   |                 |
| 3. | A budget approval process is in place; the process is carried out by the following person (persons):      | • The head of the organization.  |                 |
|    |   | • The head of the organization, together with the accounting, financial, and procurement departments.                                      |                 |
|    |   | • Financial manager (chief accountant), or the organization’s chief economist.   |                 |
|    |   | • Employees of the financial, procurement, and/or accounting departments.  |                 |
|    |   | • Other employees.   |                 |

|  |  |  |
|--|--|--|
| 4. A variance analysis (analysis of planned vs. actual expenses) is performed, and variances explained; budget (line-item budget) modifications occur as required.                       | <ul style="list-style-type: none"> <li>The organization’s administration regularly reviews financial reports, variances in planned vs. actual expenses are explained.</li> </ul>   |  |
|  | <ul style="list-style-type: none"> <li>Analysis of spending efficiency is performed by specialists in relevant units; proposals are submitted regarding efficient use of available resources, and possible sources of funding to cover the organization’s expenditures.</li> </ul> |  |
|  | <ul style="list-style-type: none"> <li>Formal budget fulfillment proposals are presented by grant coordinators or organization division heads, and financial and procurement specialists.</li> </ul>   |  |
|  | <ul style="list-style-type: none"> <li>There is a legally compliant mechanism in place for adjustment of activity, and of the budget (line-item budget) itself, based on proceeds, needs, and identified variances from the planned budget.</li> </ul>                             |  |
| 5. Budget for remuneration of specialists within the framework of a grant is reasonable in terms of actual employment and qualifications of an employee.                                 | <ul style="list-style-type: none"> <li>Surveys are conducted to determine labor market salaries of specialists at the relevant professional and qualification levels.</li> </ul>   |  |
|  | <ul style="list-style-type: none"> <li>Salary ranges are consistent with job duties performed.</li> </ul>  |  |
| 6. The organization’s budget (line-item budget) fully covers its needs for its core statutory activity, and accounts for the volume of medical care provided to the relevant population. | <ul style="list-style-type: none"> <li>Budget (line-item budget) fully meets the organization’s needs as reflected in the budget request.</li> </ul>   |  |
|  | <ul style="list-style-type: none"> <li>Line-item budget partly covers the HCF’s material and technical support needs for its current activity.</li> </ul>  |  |
|  | <ul style="list-style-type: none"> <li>Budget is reasonable given the number of patients for which HCF provides clinical services.</li> </ul>  |  |
|  | <ul style="list-style-type: none"> <li>Budget takes into account expenses incurred in providing clinical services to patients who are already being treated at HCF.</li> </ul>   |  |
|  | <ul style="list-style-type: none"> <li>Budget takes into account expenses for provision of clinical services to new patients.</li> </ul>   |  |
| Notes  |  |  |

## Section 4: FINANCIAL MANAGEMENT INFORMATION SYSTEMS

### Core Activity Areas (Competencies)

- The organization has an effective accounting system (e.g., 1C) that allows for:
  - Tracking of all accounting operations pursuant to the current laws of Ukraine, and the individual requirements of a grantor (where applicable).
  - Unit cost analysis.
  - Financial projections.
  - Tracking of expenditures against budgets, and identification of budget variances.
  - Evaluating the financial performance of subgrantees
- The organization has an accounting system that relies on a chart of accounts, categorizes expenses appropriately, and supports reporting by funding source.
- The financial system produces routine, accurate, and comprehensive fiscal reports, as well as customized reports.

- The organization has systems in place to ensure system maintenance, data security, and training of program staff.

**Questions**

- Describe the accounting system of the grantee. Does it allow for:
  - Tracking of all accounting operations pursuant to the current laws of Ukraine, and the individual requirements of a grantor (where applicable)?
  - Unit cost analysis?
  - Financial projections?
  - Tracking of expenditures against budgets, and identification of budget variances?
  - Evaluating the financial performance of subgrantees?
- The accounting system that is used to monitor spending:
  - Is it non-automated (manual) or electronic?
  - If computerized, please describe the capabilities of the program in use, particularly with regard to allocation of labor reimbursement costs, procurement of materials, sources of funding (financing), codes for economic classification of expenditures (CECE), and relevant bookkeeping accounts.
  - What are the capabilities of the financial system to produce routine, accurate, and complete, as well as customized, reports?
  - Regarding data security assurance: What is the level and extent of access to the information system?
- How are employees trained to work with the accounting system?
- Who provides technical maintenance of the system?

|    | <b>Performance Criteria</b>                                | <b>Verification Information</b>  | <b>Comments</b> |
|----|--|--|-----------------|
| 1. | The accounting system:                                     | • Has a detailed chart of accounts that allows for tracking of expenditures pursuant to the current laws of Ukraine and the individual requirements of a grantor (where applicable). |                 |
|    |  | • Allows for the tracking of expenditures pursuant to the current laws of Ukraine and the individual requirements of a grantor (where applicable).                                   |                 |
|    |  | • Allows sufficient detail for financial projections, and development and analysis of unit costs.  |                 |
|    |  | • Allows for sufficient tracking and monitoring of financial performance of the grantee, enabling the grantor to make advance payments.  |                 |
|    |  | • Allows for tracking of budgeted-vs.-actual expenses.   |                 |
| 2. | The chart of accounts provides adequate details to permit: | • Appropriate allocation of expenses by grant or funding stream.   |                 |
|    |  | • Appropriate allocation of expenses among several funding sources.  |                 |
|    |  | • Expenses planned in the chart of accounts to include advances and liquidation of advances.   |                 |
| 3. | The accounting system in use by the organization.          | • The accounting system in use is manual.  |                 |
|    |  | • Excel worksheets are used for tracking and reporting.  |                 |
|    |  | • Accounting software has been installed and is in use.  |                 |
|    |  | • The computer system and accounting application are password-protected; only authorized personnel have access.  |                 |

|       |   |   |  |
|-------|---|---|--|
| 4.    | Appropriate safeguards are in place.              | <ul style="list-style-type: none"> <li>The organization has policies describing security procedures related to working with the accounting information system.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>Computer back-ups are performed regularly; data backups are stored in a specially designated location.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>Documents or reports for manual systems are stored in a fireproof safe.</li> </ul>   |  |
| 5.    | System security, maintenance, and staff training. | <ul style="list-style-type: none"> <li>The organization has implemented a comprehensive training program for specialists working with accounting systems; organization employees have been given appropriate training.</li> </ul> |  |
|       |   | <ul style="list-style-type: none"> <li>Technical support is available.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>System is maintained by: finance department, IT department, outside vendor, or other.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>System is password-protected.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>Passwords are based on job functions within the finance department.</li> </ul>   |  |
| Notes |   |   |  |

## Section 5: ACCOUNTING SYSTEMS–PAYROLL

### Core Activity Areas (Competencies)

- The organization makes provisions for appropriate separation of payroll and payment for services provided from other accounting functions.
- Appropriate communication exists between payroll and HR related to hiring and termination. The organization regularly reconciles staff and payroll records.
- Salaries and wages are formally approved, and consistent with requirements of current laws and labor market trends for specialists of relevant qualification levels.
- The organization has a comprehensive process for payroll and payment of remuneration, payroll taxes, etc. Remuneration for employees and specialists is consistently paid.

### Questions

- What is the division of payroll duties among staff?
- What are the lines of communication among accounting, program specialists, HCF management, and HR regarding hiring, termination, determination of hours and workloads, and changes to salaries and payments of remuneration?
- Is the basis for determining salaries, remunerations, and wages compliant with requirements of current laws and labor market trends for specialists of relevant qualification levels?

|    | Performance Criteria  | Verification Information   | Comments |
|----|---|--|----------|
| 1. | Duties of individuals preparing payroll are separate from other accounting functions. | <ul style="list-style-type: none"> <li>Payroll data are reviewed and approved by HCF management and chief financial specialist (chief accountant or financial manager) after preparation.</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>There is a mechanism in place for different specialists within the financial department to cross-check verified payroll data at the time of input into the organization's accounting system.</li> </ul> |          |

|       |   |  |  |
|-------|---|--|--|
| 2.    | There is appropriate communication between payroll and HR.                                  | • HR provides written verification of names, hire dates, and salaries.   |  |
|       |   | • HR provides the accounting department with written notice of all terminations.   |  |
|       |   | • HR provides the accounting department with written notice of salary adjustments.   |  |
| 3.    | Payroll is regularly verified and compared against personnel records at specified intervals | • Payroll is compared with personnel records to verify salary and number of hours worked.  |  |
|       |   | • Discrepancies are reported to the head of HCF.   |  |
| 4.    | All salaries and pay rates are authorized and approved in writing by the head of HCF.       | • The organization keeps proper documentation regarding hiring, labor agreements, etc., sent to specialists; these agreements contain information on salaries and remunerations. |  |
|       |   | • The organization does not have agreements on hiring or involving specialists.  |  |
|       |   | • HCF does not have a system for documenting salaries/remunerations of specialists.  |  |
| 5.    | There is a system in place to record and validate employee hours worked.                    | • Employees are required to report actual hours worked.  |  |
|       |   | • Supervisors approve employee timesheets or work reports.   |  |
|       |   | • Employee timesheets and work reports are used to support calculation of salaries and paychecks.  |  |
|       |   | • The organization has a system in place to verify that paychecks are consistent with reports of hours worked.   |  |
| 6.    | The organization has a process for collecting and submitting payroll taxes.                 | • Financial staff have access to instructions regarding applicable payroll taxes.  |  |
|       |   | • Applicable payroll taxes are calculated for each pay period.   |  |
|       |   | • Applicable payroll taxes are paid on a timely basis and recorded in the accounting system.   |  |
| Notes |   |  |  |

## **Section 6: ACCOUNTING SYSTEMS–DOCUMENTATION, INTERNAL CONTROLS, AND CASH**

### **Core Activity Areas (Competencies)**

- The process of making payments is conducted pursuant to current laws, and includes a schedule of payments.
- Receipt and disbursement of funds are properly documented.

### **Questions**

- How are invoices paid? (EV)
- What is the division of duties among the organization’s financial department with respect to payment of invoices, and receipt and disbursement of funds?
- How are receipts and disbursements of funds processed? How are they documented?

|       | <b>Performance Criteria</b>  | <b>Verification Information</b>   | <b>Comments</b> |
|-------|--|---|-----------------|
| 1.    | The process of making payments is conducted properly.                  | <ul style="list-style-type: none"> <li>• Payments are authorized and/or invoices of suppliers are approved by the head of HCF and financial department specialists; such approval serves as confirmation of receipt of goods/services.</li> </ul> |                 |
|       |  | <ul style="list-style-type: none"> <li>• Documentation of accounts payable is maintained pursuant to current laws and/or grantor requirements (where applicable).</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Payments to suppliers are disbursed in a timely manner, enabling the organization to avoid paying penalties for late payments.</li> </ul>  |                 |
| 2.    | Funds are disbursed according to the schedule set forth in the budget. | <ul style="list-style-type: none"> <li>• Funds are disbursed according to a schedule that corresponds to the existing work plan, and provides for a sufficient balance of funds available to the organization.</li> </ul>                         |                 |
|       |  | <ul style="list-style-type: none"> <li>• Advance payments are carried out in a timely manner and correspond to time periods established in the work plan.</li> </ul>  |                 |
| 3.    | Disbursement of funds is properly documented.                          | <ul style="list-style-type: none"> <li>• The organization creates and keeps support documentation that corresponds to expenditures in the budget.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Documents indicate source, type, and disbursement amounts.</li> </ul>  |                 |
| Notes |  |   |                 |

## **Section 7: PROCUREMENT, PURCHASING, INVENTORY**

### **Core Activity Areas (Competencies)**

- Comprehensive procedures for procuring services, equipment, and products/supplies, including drugs and medical devices.
- Inventory management procedures. (EV)

### **Questions**

- What are the procurement/purchasing procedures and system in place?
- Do procurement procedures ensure timely receipt of goods as needed?
- What procurement oversight process does the HCF have in place?
- How are inventory and fixed assets tracked?

|    | <b>Performance Criteria</b> | <b>Verification Information</b>   | <b>Comments</b> |
|----|-----------------------------|---|-----------------|
| 1. | Procurement or purchasing.  | <ul style="list-style-type: none"> <li>• The organization has developed and approved application forms to address potential conflicts of interest; these forms have to be signed by specialists when making bids or purchases.</li> </ul> |                 |
|    |                             | <ul style="list-style-type: none"> <li>• Purchasing authority has been assigned to the purchasing division or department, or to the organization's procurement specialist.</li> </ul>   |                 |
|    |                             | <ul style="list-style-type: none"> <li>• Selection of proposals regarding purchases is carried out competitively and transparently.</li> </ul>  |                 |

|       |            |   |  |
|-------|------------|---|--|
|       |            | <ul style="list-style-type: none"> <li>The organization has developed and approved an order form for the purchase of goods or services.</li> </ul>  |  |
|       |            | <ul style="list-style-type: none"> <li>The budget-supported institution has formal procurement procedures in place for cases when the expected value of a procurement item is lower than the amount specified in the Law of Ukraine “On Public Procurement.”</li> </ul> |  |
|       |            | <ul style="list-style-type: none"> <li>Delivered goods are checked against purchase orders.</li> </ul>  |  |
|       |            | <ul style="list-style-type: none"> <li>There is a formal procedure to regulate the work of the procurement committee.</li> </ul>  |  |
|       |            | <ul style="list-style-type: none"> <li>All minutes of procurement committee meetings are available for examination.</li> </ul>  |  |
|       |            | <ul style="list-style-type: none"> <li>Do requests for purchase of goods or services indicate criteria for selection of the supplier on the basis of price, quality, and terms of delivery?</li> </ul>  |  |
|       |            | <ul style="list-style-type: none"> <li>Requests for purchasing are signed by head of the organization, and the head of the financial and/or procurement departments.</li> </ul>   |  |
| 2.    | Inventory. | <ul style="list-style-type: none"> <li>The organization uses a clear system for tracking current inventory, particularly for drugs and medical devices.</li> </ul>  |  |
|       |            | <ul style="list-style-type: none"> <li>The organization has developed and implemented a system for checking and verifying partial deliveries.</li> </ul>  |  |
|       |            | <ul style="list-style-type: none"> <li>A commission regularly conducts physical verification of inventory.</li> </ul>   |  |
| Notes |            |   |  |

## Section 8: FINANCIAL MONITORING AND PROGRAM OVERSIGHT

### Core Activity Areas (Competencies)

- The organization conducts an annual external audit of its financial system.
- The organization’s last audit report includes no deficiencies with regard to compliance, completed purchases of materials, or information about questionable costs of goods or services.
- Minutes of meetings of financial department specialists at the end of the audit (where applicable) indicate that external audit reports have been submitted to the organization’s management.
- The organization has either an internal audit department or an internal auditor who conducts an independent review of financial systems and processes.
- A comprehensive fiscal monitoring tool is used to verify fiscal compliance on the part of the organization and its grantee(s).
- The organization has a process in place for responding to audit findings, one that includes development or implementation of a corrective action plan, and evaluation of improvements.

### Financial Reporting & Cash Flow

- Directors of the organization and the financial department receive, review, and certify financial reports on a regular basis.
- The organization has a cash management system that entails forecasting of cash needs.
- The organization has sufficient cash reserves to sustain its operations during periods when financing is delayed.

## Questions

### *Audits (Internal & External)*

- Are there external audit processes in place?
- Have the last financial audit and its results been submitted to the head of the organization?
- Are there internal audit processes in place?
- Is there a fiscal monitoring tool in use to verify fiscal compliance, both for self-assessment of the organization, and for the grantee's organization (where applicable)?
- Has a corrective action plan been developed and implemented in response to audit findings? Are improvements under the plan being monitored and evaluated?

### *Financial Reporting & Cash Flow*

- Are financial reports being distributed to the head of the organization? Which reports? How often?
- How is cash flow managed during delays in financing?

### **Audit (Internal & External)**

|    | <b>Performance Criteria</b>   | <b>Verification Information</b>  | <b>Comments</b> |
|----|---|--|-----------------|
| 1. | The organization has internal and external review processes, including a management plan to respond to audit findings.  | <ul style="list-style-type: none"> <li>• Finance manager (chief accountant) conducts internal reviews.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Accountant conducts periodic internal reviews.</li> </ul>   |                 |
|    |   | <ul style="list-style-type: none"> <li>• The heads of the HCF and financial department jointly conduct periodic internal reviews.</li> </ul>   |                 |
|    |   | <ul style="list-style-type: none"> <li>• Internal audits are conducted periodically.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• External audits are conducted annually.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• A written plan has been developed in response to audit findings.</li> </ul>   |                 |
| 2. | There is a regular schedule that ensures that all grantees will receive annual visits (where applicable); monitoring of their financial activity is conducted during such visits. |  |                 |
| 3. | A fiscal monitoring instrument, approved by the heads of the organization and financial department, is in use.  |  |                 |
| 4. | The fiscal monitoring instrument entails reviewing the following:   | <ul style="list-style-type: none"> <li>• Accounting system.</li> </ul>   |                 |
|    |   | <ul style="list-style-type: none"> <li>• Cash balance.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Fiscal reports and financial statements.</li> </ul>   |                 |
|    |   | <ul style="list-style-type: none"> <li>• Completed audits.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Follow-up on an auditor's findings.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Effectiveness of accounts receivable management.</li> </ul>   |                 |
|    |   | <ul style="list-style-type: none"> <li>• Calculation of days in accounts receivable.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Reviewing of age of receivables.</li> </ul>   |                 |
|    |   | <ul style="list-style-type: none"> <li>• Status of payroll and remuneration liabilities.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Budget management system.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Client/patient eligibility policies.</li> </ul>   |                 |
|    |   | <ul style="list-style-type: none"> <li>• Whether staffing is adequate for fiscal management.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Adherence to policies and procedures.</li> </ul>  |                 |
|    |   | <ul style="list-style-type: none"> <li>• Budget management and oversight:                             <ul style="list-style-type: none"> <li>– Actual vs. budgeted items.</li> <li>– Variances between budgeted and actual expenses are tracked and can be justified.</li> </ul> </li> </ul> |                 |

|  |  |   |  |
|--|--|---|--|
|  |  | – Payroll expenses are verified by program directors.                           |  |
|  |  | • Supporting documentation is on file for all transactions.                     |  |
|  |  | • Separation of duties is appropriate.  |  |
|  |  | • Aged accounts receivable and payable reports.                                 |  |
|  |  | • Cash flow statement/cash balance.   |  |
|  |  | • Bank account reconciliations.   |  |
|  |  | • Review of internal and external audits, including management action plans.    |  |
|  |  | • Lease contracts.  |  |
|  |  | • Fixed assets are tagged and accounted for. Inventory listings are up-to-date. |  |

### Financial Reporting & Cash Flow

|       | Performance Criteria | Verification Information   | Comments |
|-------|----------------------|--|----------|
| 1.    | Financial reports.   | <ul style="list-style-type: none"> <li>List of financial reports is regularly submitted to organization leadership.</li> <li>Financial reports are accompanied by narrative highlighting areas of concern (e.g. current ratio).</li> <li>Financial staff participate in meetings of the organization's leadership and program coordinators.</li> </ul> |          |
| 2.    | Cash flow.           | <ul style="list-style-type: none"> <li>Current ratio (current assets/current liability).</li> <li>Working capital to total assets ratio (working capital/total assets).</li> <li>Average number of days between submission of a drawdown and of funds.</li> </ul>  |          |
| Notes |                      |  |          |

## Section 9: GRANTS/CONTRACT MANAGEMENT (Organization That Is or Plans to Become a Grantor)

### Core Activity Areas (Competencies)

- There is a comprehensive grants management system that sets forth a detailed goods or services procurement process to solicit, select, and renew funding relationships with new and existing grantees; a process to assess performance of grantees; and a system for comprehensive file maintenance.

### Questions

- Is there a grants management system in place that includes a bid selection process, oversight or management of subgrantees, and file maintenance?
- Do subgrantees submit document lists, along with signed agreements, on both regular and periodic bases?

|       | <b>Performance Criteria</b>  | <b>Verification Information</b>   | <b>Comments</b> |
|-------|--|---|-----------------|
| 1.    | Identification and selection of subgrantees.   | <ul style="list-style-type: none"> <li>• Selection requirements are made available to interested subgrantees in advance.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Qualified independent reviewers participate in evaluation and/or selection; the approval process for reviewers includes screening for conflicts of interest.</li> </ul>                                |                 |
|       |  | <ul style="list-style-type: none"> <li>• The organization maintains records of the scoring or selection process; information is maintained about the status of each applicant, as assigned by each reviewer, per selection criteria.</li> </ul> |                 |
|       |  | <ul style="list-style-type: none"> <li>• Selection decisions are approved by management prior to issuance of final notices.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Written notices of selection or rejection are sent to all applicants.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• A mechanism has been developed for notifying applicants of the reasons for rejection.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• There are documents to clarify for subgrantees the requirements for receipt of funding.</li> </ul>   |                 |
| 2.    | Each grantee has a written contract that specifies:  | <ul style="list-style-type: none"> <li>• The nature and number of services to be provided.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Eligibility requirements for client enrollment or visits.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Line-item budget and/or payment rates per service.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• The nature and frequency of required narrative reporting.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Data collection criteria and reporting expectations.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Processes for advance or reimbursement payments.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Invoicing procedures.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Program monitoring processes and timeframes.</li> </ul>  |                 |
| 3.    | There is a system in place to document and track the contract status of each subgrantee. Complete files are maintained that include the following: | <ul style="list-style-type: none"> <li>• Quality management expectations.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Notice of funding award.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Approved budget and budget modifications.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Site visit reports, including findings and recommendations.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Records relating to procedural guidance or technical assistance.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Fiscal reports.</li> </ul>   |                 |
|       |  | <ul style="list-style-type: none"> <li>• Performance reports.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Subgrantee invoices and supporting documentation for expenditures.</li> </ul>  |                 |
|       |  | <ul style="list-style-type: none"> <li>• Tracking of payments to the subgrantee, and the remaining balance of the grant.</li> </ul>   |                 |
| Notes |  |   |                 |

## Annex 3. HIV Counseling and Testing Module

### INTRODUCTION

The HIV Counseling and Testing Module of the CLASS tool is a guide, not a checklist, for reviewers conducting assessments of HCF and other facilities providing HIV counseling and testing (HCT) services. This module will be used for assessment of all HCT service provision models existing in HCF (of all ownership patterns) and beyond, under programs financed by the local budget, the Global Fund to Fight AIDS, Tuberculosis and Malaria, or other sources.

This module covers the agenda of voluntary counseling and testing for HIV; provision of integrated services with health care provider-initiated counseling and testing; and HCT services provided in mobile clinics and at NGOs, including mobile HCT services provided in places where representatives of at-risk groups gather, and in cases where patients in prevention, treatment, and care programs go to NGO clinics to obtain services.

This HIV Counseling and Testing Module is divided into seven sections:

- Facility, Staff, and Services
- HCT Protocols and Procedures
- Laboratory Services (HIV Testing)
- System of Interaction and Provision of Services by Referral
- Community Mobilization, Support, and Promotion of HCT
- Support for Decentralization of HCT Services
- HCT Quality Management System

Each section begins with a list of core activity areas (competencies). This list is followed by a series of questions that can be used in discussions with representatives of the facility. Verification criteria for the core activity areas and questions are provided, along with space for making notes. There is no need to complete all the tool sections in the order presented, but the reviewer should proceed with flexibility, to accommodate the time and availability of staff for interviews.

This module is created for assessment of HCT services provided on HCF premises, as well as in other places—e.g., community-based voluntary HCT, mobile HCT clinic, HCT per initiative of a clinical worker, and HCT services provided by NGOs.

(The Community Mobilization section of this tool may not apply to integrated HCT services provided on HCF premises.)

The Clinical Module can also be used to assess Laboratory HCT services. The term “mobile unit” refers to all individual support services provided by NGOs, including mobile clinics, testing in places where representatives of at-risk groups gather, at needle exchange points (NEP), and in-home care.

It is assumed that approximately four hours will be spent at each site in order to allow for assessment using in-depth interview methods. Priority areas for carrying out an assessment are selected prior to a facility visit. Selection of these areas should be based on previous assessments (if any), and statistical and other information that describes the activity of a facility, and was obtained during preliminary consultations.

## Section 1. FACILITY, STAFF, AND SERVICES

*Note: This assessment is for HCT services provided on the premises of HCF and beyond (voluntary HCT, mobile HCT clinics, HCT per initiative of a clinical worker, HCT services provided by NGOs, at sites where members of at-risk groups gather, and in cases where patients in prevention, treatment, and care programs come to the HCF to obtain services).*

### Core Activity Areas (Competencies)

- The facility provides at least one of the following services:
  - Integrated health care provider-initiated counseling and testing services.
  - Voluntary HCT.
  - HCT services through mobile units, including at sites where members of at-risk groups gather, and in cases where patients come to the HCF to obtain services.
- HCF provides services to all populations: adults, children and adolescents, family couples, pregnant women, persons in close contact with HIV-positive people, other populations, and members of at-risk groups.
- The professional qualifications and training levels of employees (clinical and non-clinical specialists, social workers, and volunteers) correspond to positions held and duties performed.
- Operating hours, the number of staff, the range of services offered, and the premises available enable the HCF to ensure confidentiality, satisfying both patient needs and overall demand for HCT services.

### Questions

- What HCT services are provided to patients by the facility on site? What services are provided by referral or through mobile units (including in places where members of at-risk groups gather)?
- How do the HCF and employees organize work to ensure confidentiality and satisfaction of patient needs with regard to HCT services?
- How exactly is the system for referral of HCT services organized?
- How are adequate qualification, training, mentorship support, and supervision secured for HCT services?

|    | Performance Criteria                   | Verification Information   | Comments |
|----|--|--|----------|
| 1. | Range of HCT services provided at HCF. | • Health care provider-initiated HCT services.   |          |
|    |  | • Voluntary HCT services.  |          |
|    |  | • At sites (NEPs, mobile units) where members of at-risk groups gather.  |          |
|    |  | • HCT for persons in close contact with an HIV-positive patient (e.g., family, children, partners, cohabitants). |          |
|    |  | • Crisis counseling (on receiving HIV-positive status).  |          |
|    |  | • Counseling on status disclosure; encouragement to test persons in close contact with the patient.              |          |
|    |  | • Use of rapid tests.  |          |
|    |  | • Enzyme-linked immunosorbent assay (ELISA) tests.   |          |
|    |  | • Confirmatory tests for HIV.  |          |

|    |  |   |  |
|----|--|---|--|
| 2. | Target groups receiving HCT services.                  | <ul style="list-style-type: none"> <li>Adults aged 18 and above who are not members of at-risk groups.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>Partners of HIV-positive patients (except for pregnant women and their partners).</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>Children up to 11 years of age; adolescents up to 18 years of age.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>Pregnant women and their partners.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>At-risk groups: <ul style="list-style-type: none"> <li>Men who have sex with men (MSM)</li> <li>Commercial sex workers (CSWs)</li> <li>People who inject drugs (PWID)</li> <li>Migrants</li> <li>Prisoners</li> <li>People using the services of CSWs</li> <li>Street children</li> </ul> </li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>Recipients of blood products and donor organs.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>People in close contact with HIV-positive patients (e.g., family, partners, cohabitants, children).</li> </ul>   |  |
| 3. | Integrated HIV prevention services.                    | <ul style="list-style-type: none"> <li>Clinical workers at risk for on-the-job exposure.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>Counseling (including group and partner counseling) of patients on risks of HIV exposure.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>Partner counseling on HIV risk reduction for discordant couples.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>Providing patients with barrier contraception (condoms).</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>Providing patients with syringes, alcohol wipes, etc.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>Providing on-site treatment, or referring to another facility or organization for treatment.</li> </ul>  |  |
| 4. | Staff capacity, qualifications and levels of training. | <ul style="list-style-type: none"> <li>Screening for sexually transmitted infection (STI), or referring to another facility or organization for screening.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>Staff (clinical and non-clinical workers, social workers, and volunteers) have HCT training and certification (if provided for), and in particular are familiar with the following: <ul style="list-style-type: none"> <li>Specifics of counseling members of at-risk groups (e.g., MSM, PWID, CSWs).</li> <li>Specifics of HCT for children and adolescents.</li> <li>HCT for partners, including pregnant women and other partners, as well as discordant couples.</li> <li>Counseling those in close contact with HIV-positive patients (e.g., family, partners, cohabitants, children) on status disclosure, and encouraging them to get tested.</li> <li>Counseling HIV-positive people and those closest to them on acceptance and understanding of the disease, and initiation of ART.</li> <li>Health care provider-initiated counseling and testing.</li> </ul> </li> </ul> |  |
|    |  | <ul style="list-style-type: none"> <li>Employees are familiar with the HIV rapid-testing technique and quality assurance methods.</li> </ul>  |  |

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|    |   | <ul style="list-style-type: none"> <li>• Employees are familiar with crisis counseling techniques and procedures.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>• Employees are familiar with group counseling techniques and procedures.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• Employees have ready access to mentorship support, counseling, and supervision from specialists at higher-level institutions, whether directly, by phone, or through other means of communication.</li> </ul> |  |
|    |   | <ul style="list-style-type: none"> <li>• HCF has sufficient numbers of staff (clinical and non-clinical workers, including psychologists, volunteers, and social workers) to meet HCT service needs.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• Employees involved in HCT have ready access to professional burnout prevention services.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>• HCF management uses principles of motivational management with employees who provide HCT services.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>• There is minimal turnover of trained and qualified staff at HCF.</li> </ul>   |  |
| 5. | Operating hours and broad access to HCT services. | <ul style="list-style-type: none"> <li>• Operating hours of the facility and specific employees are clearly and prominently displayed.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• Operating hours are convenient for patients—i.e., patients can receive services at times that are convenient for them (e.g., before 9:00 a.m., after 6:00 p.m., and/or on weekends and holidays).</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• The facility has a well-defined and approved HCT patient pathway.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• All requirements of satisfactory sanitary and epidemiological modes and infection control are adhered to.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• Confidentiality is ensured for clients/patients as part of HCT, both within the facility and at mobile units.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• The facility has a separate waiting area for patients, ensuring confidentiality and preventing stigmatization.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>• Wait times for HIV test results are minimal, and do not result in patient dropouts.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• HCT services are provided for free to all populations.</li> </ul>   |  |
| 6. | Rapid testing.                                    | <ul style="list-style-type: none"> <li>• Rapid testing is accessible for all populations.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>• Inventory of rapid test kits allows complete satisfaction of testing needs.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• There is a system in place to order, receive, and monitor the use of rapid tests (to accommodate their short shelf life).</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• The facility has experience with receiving humanitarian aid to secure rapid testing.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>• Rapid testing is used at mobile units.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>• There is an effective and clear system in place for post-rapid-test referral of people with HIV-positive results for medical follow-up and treatment.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>• Clinical and/or non-clinical workers are trained in the rapid testing procedure.</li> </ul>   |  |

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| 7.    | Activities for HIV-negative persons. | <p>Patients with negative HIV-status are counseled on ways to reduce their risk of contracting HIV:</p> <ul style="list-style-type: none"> <li>• Use of barrier contraception (condoms).</li> <li>• Moderation of sexual activity, and in number of sexual partners.</li> <li>• Delaying sexual activity (for people aged 13 and above).</li> <li>• STI diagnosis and treatment.</li> <li>• Use of sterile disposable tools for intravenous injection of psychoactive substances.</li> <li>• PWID: prescription of opioid substitution therapy (OST), counseling on abstaining from use of psychoactive substances, and/or referral to rehabilitation programs.</li> <li>• Regular testing for HIV and other infections at certain intervals.</li> <li>• Referral to harm-reduction programs.</li> </ul> |  |
| Notes |                                      |  |  |

## Section 2. HCT PROTOCOLS AND PROCEDURES

### Core Activity Areas (Competencies)

- Clinical and non-clinical workers, including psychologists, volunteers, and social workers who provide HCT services, have ready access to documentation of relevant regulations that govern the provision of HCT (including directives from MOH, protocols, and guidelines), and use regularly in their work.

### Questions

- What regulations, including HCT protocols and guidelines, are followed by clinical and non-clinical workers, psychologists, and volunteers?
- How does the existing mechanism for providing HCT services ensure consistency with current protocols, guidelines, and international standards?
- What local protocols and procedures for HCT have been developed and implemented?
- What system is in place to educate employees with regard to requirements of the current HCT regulatory framework—in particular, concerning maintenance of primary medical records and elaboration of reports?
- How is staff familiarized with changes to the regulatory framework governing provision and documentation of HCT—in particular, concerning maintenance of primary medical records and elaboration of reports?
- What mechanisms are in place governing receipt, analysis, verification, and submission of HCT reports?

|    | Performance Criteria                              | Verification Information  | Comments |
|----|---|---|----------|
| 1. | HCF uses standardized and approved HCT protocols. | <ul style="list-style-type: none"> <li>• Approved HCT management protocols have been printed and are posted.</li> <li>• An excerpt from approved protocols addressing only HCT operating procedures is readily accessible.</li> <li>• Available printed copies of HCT regulations are reviewed and updated as needed.</li> <li>• Required staff training on HCT regulations is in place.</li> </ul> |          |

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|       |   | <ul style="list-style-type: none"> <li>• Ongoing evaluation of staff knowledge of HCT protocols, algorithms, procedures, and current regulations is in place.</li> <li>• A clear system is in operation for transferring HIV test results from the lab to HCT specialists.</li> <li>• The system for transferring HIV test results ensures patient confidentiality.</li> </ul>  |  |
| 2.    | Management of primary medical records and reports.        | <ul style="list-style-type: none"> <li>• HCT registration logs are maintained pursuant to regulations.</li> <li>• Patient risk groups are properly coded.</li> <li>• Written instructions for proper group coding are readily accessible.</li> <li>• Referral and test result forms comply with requirements.</li> <li>• Storage of primary medical records ensures confidentiality, and restricts access to information.</li> <li>• Data in primary medical records is accurate and complete, and enables generation of required reports.</li> <li>• Reports are generated pursuant to the current regulatory framework.</li> <li>• The facility conducts training on report generation.</li> <li>• Reports contain completion and submission dates, seals, and signatures.</li> </ul>   |  |
| 3.    | Verification, analysis, and submission of reporting data. | <ul style="list-style-type: none"> <li>• Appropriately trained specialists are assigned responsibility for collection, summarization, and analysis of HCT reporting data.</li> <li>• Reporting data is analyzed in detail.</li> <li>• Reporting data analysis findings are discussed at meetings.</li> <li>• A clear system is in place for identifying and analyzing possible errors.</li> <li>• Computers and software are used for generation of reporting data.</li> <li>• Reporting data is constantly verified (for accurateness and completeness).</li> <li>• Reporting forms are submitted by the deadlines specified in the regulations.</li> <li>• Advisory support can be obtained from specialists at higher-level institutions concerning the processes of data collection, analysis, and submission, generation of reporting forms, etc.</li> </ul> |  |
| Notes |   |   |  |

### Section 3. LABORATORY SERVICES (HIV Testing)

#### Core Activity Areas (Competencies)

- The network of laboratories enables full satisfaction of requirements for quality and promptness in HIV testing.
- Lab staff skills, qualifications, and expertise enable HCF to meet HIV testing volume requirements.
- The facility has sufficient space for labs or rapid testing points, as well as for storage of materials, equipment, and reagents, etc.
- HIV tests and appropriate controls are carried out according to established operating procedures.
- A cold chain for reagents is provided directly at the facility and/or in mobile clinics.
- Regular internal and external test quality controls are in place.
- Laboratory staff are trained in fundamentals of waste disposal and post-exposure prophylaxis (PEP).

#### Questions

- What training and certification procedures are provided for lab staff?
- How does the organization delivering HCT services obtain advisory and/or technical assistance from higher-level labs concerning diagnostics, monitoring, and quality assurance for tests conducted and supply of reagents?
- What systems are used in the facility to provide a cold chain for reagents?
- What processes are used to ensure control of test quality, and uninterrupted supply of reagents and tests?
- What infection control and PEP procedures are used in the lab unit?
- What are the key procedures applied in case of an emergency at the HCT site? At the mobile unit? At the NGO?

|    | Performance Criteria                                   | Verification Information  | Comments |
|----|--|---|----------|
| 1. | Staffing, qualification levels, and training of staff. | • The lab unit at the facility has sufficient staffing to fully meet its operational needs.   |          |
|    |  | • Lab staff possess the qualifications required for the positions they occupy.  |          |
|    |  | • All lab staff are appropriately trained, and have opportunities to improve their skills.  |          |
|    |  | • Advisory support from specialists at higher-level labs can be obtained.   |          |
|    |  | • Needs for additional training and skills for lab employees are constantly analyzed.   |          |
|    |  | • Lab specialist knowledge of HIV testing techniques, including rapid testing, is constantly analyzed.  |          |
| 2. | Inventory and equipment.                               | • The lab unit has sufficient space to ensure the required range of diagnostic services.  |          |
|    |  | • Modern lab equipment meets operating needs concerning the volumes and range of tests.   |          |
|    |  | • A maintenance agreement is in place to ensure regular inspection and maintenance of lab equipment and tools.                                      |          |
|    |  | • Maintenance records for lab equipment and tools are kept, documenting equipment inspections, routine maintenance, faults/breakdowns, and repairs. |          |

|    |   |   |  |
|----|---|---|--|
|    |   | <ul style="list-style-type: none"> <li>Detailed estimates of lab equipment inspection and maintenance costs are prepared, and then submitted to the HCF's financial department.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>Technical condition of lab equipment and tools is constantly assessed.</li> </ul>  |  |
| 3. | Mentorship support and supervision.   | <ul style="list-style-type: none"> <li>An agreement governing collaboration between HCF and NGOs is in place, specifying that lab employees supervise HCT points within mobile units.</li> <li>Designated lab specialists makes field visits to monitor and support counselors at mobile units, and HCT services delivery counselors at NGOs.</li> <li>An agreement governing cooperation between HCF and NGO specifies that, at least twice a year, HCF specialists evaluate the knowledge of mobile unit and NGO specialists concerning the HIV rapid testing methodology and algorithm.</li> <li>Quality evaluation mechanisms have been developed and implemented for HIV testing at mobile units—for example, every tenth blood sample from each mobile unit counselor is sent to the HCF lab to confirm rapid test results, including negative results.</li> <li>On-the-job opportunities for training (internships) are provided for lab unit specialists from lower-level HCFs and mobile units.</li> <li>Lab specialists conduct monitoring visits to lower-level HCF labs where HIV tests are performed. Findings of these visits are appropriately documented, and implementation of provided recommendations is regularly checked.</li> </ul> |  |
| 4. | Order, receipt, storage, and monitoring of use of test kits and medical products. | <ul style="list-style-type: none"> <li>A clear, understandable system is in place for generation of procurement orders for test kits and medical products for the lab unit.</li> <li>The frequency of ordering ensures uninterrupted provision of HIV testing services. There are no cases of shortage of test kits or medical products.</li> <li>Conditions for receipt and storage of test kits and medical products are consistent with the current regulatory framework.</li> <li>Compliance with storage conditions (e.g., temperature, humidity) for test kits and medical products is appropriately documented.</li> <li>A clear system is in place for constant monitoring of lab inventory of test kits and medical products, to ensure they are used before the end of their shelf life. No cases of inefficient use of available stock are recorded.</li> </ul>  |  |
| 5. | Waste disposal, occupational, safety, and infection control.                      | <ul style="list-style-type: none"> <li>Lab unit and mobile units are provided with the sufficient numbers of individual protective gear (e.g., gloves, eyewear, suits/robes, coveralls, masks).</li> <li>Disposal of waste, including used biological materials, is in compliance with current regulations.</li> <li>A signed lab unit waste disposal contract is in place.</li> </ul>  |  |

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|-------|---|--|--|
|       |   | <ul style="list-style-type: none"> <li>The lab is fitted with equipment for deactivation of potentially hazardous waste and used materials.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>A local protocol has been developed for waste disposal at mobile units.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>Designated specialists are assigned responsibility for occupational safety and infection control.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>Lab and mobile unit specialists with credits in occupational safety and infection control requirements have been trained in working with potentially hazardous biological materials.</li> </ul> |  |
|       |   | <ul style="list-style-type: none"> <li>Occupational safety, infection control, and waste disposal procedures are printed and displayed in accessible areas (e.g., on walls, stands).</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>Lab and mobile units are provided with enough containers for waste collection and disposal.</li> </ul>  |  |
| 6.    | Ensuring post-exposure prophylaxis (PEP). | <ul style="list-style-type: none"> <li>Clinical workers who work with blood and other biological liquids use all required safety and protective gear.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>There is a printed PEP protocol or operating procedure.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>PEP operating procedures are printed and displayed in accessible areas (e.g., on walls, stands).</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>Lab and mobile unit staff are trained at regular intervals in prevention of occupational exposure and PEP.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>Ready access to antiretroviral (ARV) drugs for PEP is ensured within timelines consistent with protocols.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>Each case of emergency and PEP is appropriately documented.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>Causes of emergencies, and actions taken to prevent on-the-job exposure are analyzed.</li> </ul>  |  |
| Notes |   |  |  |

#### **Section 4. SYSTEM OF INTERACTION AND PROVISION OF SERVICES BY REFERRAL**

##### **Core Activity Areas (Competencies)**

- There are signed agreements governing cooperation and referral of clients/patients for medical follow-up, prevention, care, and support between HCF and NGOs.
- An effective system is in operation for referral of HIV-positive clients from mobile units/NGOs to HCF.
- Client/patient pathways are developed and approved by all stakeholders for receipt of medical follow-up, prevention, care, and support services between HCF and NGOs.

##### **Questions**

- What referral system is in place to ensure the required range of services of medical follow-up, prevention, care, and support?
- How is tracking ensured for referral of clients/patients to medical follow-up, prevention, care, and support services?

|       | <b>Performance Criteria</b>              | <b>Verification Information</b>   | <b>Comments</b> |
|-------|--|---|-----------------|
| 1.    | Interaction between HCF and NGO for HCT. | <ul style="list-style-type: none"> <li>• Agreements on cooperation, together with a multidisciplinary approach to services, ensure a clear system of interaction between HCF and NGO.</li> <li>• A patient pathway is developed; the pathway enables easy understanding of the sequence of actions of all entities, from enrollment of the patient in HIV testing and obtaining an HIV-positive test result, to administering treatment of HIV.</li> <li>• The referral system takes into account patient needs in screening for TB, STI, viral hepatitis (VH), etc.</li> <li>• The patient pathway incorporates satisfaction of patient needs for prophylactics (e.g., condoms, sterile wipes, syringes).</li> <li>• Agreements provide for information exchange between HCF and NGOs concerning clients referred for medical care from mobile units to HCF.</li> <li>• Agreements governing cooperation between HCF and NGOs take into account the need to provide medical care for patients testing positive for HIV.</li> </ul> |                 |
| 2.    | Tracking referrals.                      | <ul style="list-style-type: none"> <li>• A unified referral form is applied (using counterfoils).</li> <li>• A clear system is in place to ensure documentation of issued referrals.</li> <li>• Information about the number of clients referred for medical care from mobile units (NGOs) to HCF is frequently cross-checked.</li> </ul>   |                 |
| Notes |  |   |                 |

## **Section 5. COMMUNITY MOBILIZATION, SUPPORT, AND PROMOTION OF HCT**

### **Core Activity Areas (Competencies)**

- HCF and partner organizations (e.g., NGOs, State Service for Family, Youth and Sport (SSFYS), educational institutions) have a comprehensive strategy for raising public awareness regarding HIV prevention and HCT.
- Information is disseminated about the advantages of early detection of HIV, and access to treatment and care.
- There are separate approaches to generating information about HCT for the public, young pupils, and members of at-risk groups in accordance with their needs.

### **Questions**

- What strategies are used to raise awareness about HIV prevention, and encourage public involvement in HCT?
- With which organizations, and on what basis, does the facility interact to disseminate information about HCT, and gain access to members of at-risk groups?

|       | <b>Performance Criteria</b>                            | <b>Verification Information</b>   | <b>Comments</b> |
|-------|--|---|-----------------|
| 1.    | Strategies for dissemination of information about HCT. | <ul style="list-style-type: none"> <li>• Social marketing and activities involving local media are introduced: <ul style="list-style-type: none"> <li>– Electronic media (radio, TV, web)</li> <li>– Printed matter (flyers, information leaflets, brochures, placards)</li> </ul> </li> <li>• Involvement of members of most at-risk populations (MARPs), youth, and other populations in community level HCT provided by clinical or social workers, educators, outreach workers, etc.: <ul style="list-style-type: none"> <li>– Peer-driven counseling for MARPs</li> <li>– Open dialogue, including in the press</li> <li>– Informal discussion or lectures for young pupils</li> </ul> </li> </ul> |                 |
| 2.    | Information materials about HIV-related issues.        | <ul style="list-style-type: none"> <li>• Key methods of HIV transmission, prevention, HCT, treatment, and care are covered.</li> <li>• Problems of stigmatization and discrimination against HIV-positive people are highlighted.</li> <li>• Issues of gender equality and violence are raised.</li> <li>• Materials use plain, easy-to-digest language and account for the specifics of each target group.</li> </ul>  |                 |
| Notes |  |   |                 |

## Section 6. SUPPORT FOR DECENTRALIZATION OF HCT SERVICES

### Core Activity Areas (Competencies)

- There is a clear strategy and plan in place to expand the network of HCT services.
- Mentorship support and supervision are ensured for the network of HCT sites.

### Questions

- What strategy is being used to expand HCT services?
- How are needs for expansion of the network of HCT sites assessed?
- How are inventory and staffing needs for expansion of the network of HCT sites assessed and satisfied?
- How are mentorship support and supervision ensured for counselors in the network of HCT sites?
- How are performance and service quality at decentralized HCT sites monitored?

|    | <b>Performance Criteria</b>                              | <b>Verification Information</b>  | <b>Comments</b> |
|----|--|--|-----------------|
| 1. | Strategies for further decentralization of HCT services. | <ul style="list-style-type: none"> <li>• There is a clear plan in place for expansion of the network of HCT services.</li> <li>• Expansion of the network of HCT services is based on needs assessment of services for all populations.</li> <li>• Expansion of the network of HCT services takes into consideration the need for those services among members of MARPs.</li> <li>• Clients/patients travel no more than 10 km to receive HCT services.</li> </ul> |                 |

|       |   |  |  |
|-------|---|--|--|
| 2.    | Needs assessment and ensuring expansion of the network of HCT sites.  | <ul style="list-style-type: none"> <li>• Requirements for expansion of HCT services are determined on the basis of the state of the HIV epidemic and where members of MARPs are concentrated.</li> <li>• Tools are developed to assess the inventory and staffing needs of new HCT sites.</li> <li>• The training requirements for counselors of decentralized HCT sites are assessed.</li> <li>• There are mechanisms in place to satisfy the inventory and staffing needs of new HCT sites.</li> <li>• Clear mechanisms and tools are developed to ensure that confidentiality is preserved during transportation of blood samples to HIV test labs and delivery of results to clinics and clients/patients.</li> </ul>  |  |
| 3.    | Mentorship support and supervision of HCT sites.                      | <ul style="list-style-type: none"> <li>• Counselors in the network of HCT sites have appropriate training and certification.</li> <li>• Counselors at decentralized HCT sites can readily obtain HCT mentorship support from counselors at higher-level institutions, whether directly, by phone, or through other means of communication.</li> <li>• On-the-job internships are available to counselors at decentralized HCT sites.</li> <li>• Performance of counselors at decentralized HCT sites is supervised on a regular basis by specialists from higher-level facilities.</li> <li>• A schedule is developed for specialists from the main facility to conduct mentorship visits to decentralized HCT sites.</li> <li>• All mentorship and supervisory visits are documented.</li> <li>• Decentralized HCT sites have ready access to the web.</li> </ul> |  |
| 4.    | Monitoring of performance, and assessment of quality of HCT services. | <ul style="list-style-type: none"> <li>• Instruments are developed for monitoring and evaluation of quality of services at decentralized HCT sites.</li> <li>• There is a clear schedule for specialists from the main facility to conduct monitoring visits to decentralized HCT sites.</li> <li>• The monitoring visit process requires that specialists at decentralized HCT sites be informed about the purpose and objectives of the visit.</li> <li>• Monitoring visits are documented. Certificates can be issued when visits are completed.</li> <li>• Implementation of proposals for improvement of HCT services subsequent to monitoring visits is controlled.</li> </ul>   |  |
| Notes |   |  |  |

## Section 7. HCT QUALITY MANAGEMENT SYSTEM

### Core Activity Areas (Competencies)

- Protocols and procedures are developed and implemented to ensure continuous HCT quality evaluation and improvement.
- HCT quality indicators are developed for performance evaluation.
- A process of continuous HCT quality improvement is established.

### Questions

- What monitoring system is used to identify problems in HCT performance?
- How are documents maintained under this system?
- What systems are used to improve the quality of HCT?

|    | <b>Performance Criteria</b>                          | <b>Verification Information</b>   | <b>Comments</b> |
|----|--|---|-----------------|
| 1. | Protocols and procedures for HCT quality management. | <ul style="list-style-type: none"> <li>• Protocols and procedures are developed for HCT.</li> <li>• A detailed client/patient pathway is developed for HCT services.</li> <li>• Job instructions for HCT specialists contain comprehensive information about HCT procedures.</li> <li>• Indicators are developed for evaluation of quality of HCT services at the HCF.</li> </ul>   |                 |
| 2. | Staff performance evaluation.                        | <ul style="list-style-type: none"> <li>• Quality evaluation criteria are developed for measuring counselor performance.</li> <li>• Performance evaluation records submitted confirm that evaluations are not merely a pro-forma process.</li> <li>• HCF administration performs reviews of HCT counselor records.</li> <li>• Regular (at least quarterly) discussion of counselor performance quality takes place at regular or working meetings on HCT.</li> </ul>   |                 |
| 3. | Assessment of client/patient satisfaction levels.    | <ul style="list-style-type: none"> <li>• Client/patient questionnaires are developed and introduced as part of HCT practice.</li> <li>• Client/patient satisfaction is regularly monitored through polling and/or surveys.</li> <li>• Client/patient satisfaction survey findings are discussed at regular or HCT working.</li> <li>• Decisions regarding HCT quality improvement take into consideration client/patient satisfaction with HCT services.</li> </ul>   |                 |
| 4. | HCT quality evaluation and improvement system.       | <ul style="list-style-type: none"> <li>• Achievement of HCT quality indicators (both local and national, on program implementation) is regularly evaluated.</li> <li>• Regular (at least quarterly) or working meetings are held to discuss HCT quality.</li> <li>• The minutes of all regular or working meetings on HCT quality evaluation and improvement are recorded.</li> <li>• HCT quality decisions made during regular or working meetings are documented, with their implementation being governed by those documents.</li> </ul> |                 |

|  |  |   |  |
|--|--|---|--|
|  |  | <ul style="list-style-type: none"> <li>Designated persons are assigned responsibility for continuous HCT quality evaluation at the facility, as well as implementation of decisions made during meetings or working meetings on evaluation of HCT quality.</li> </ul> |  |
| 5.   | Staff involvement in quality improvement evaluation and decision-making. | <ul style="list-style-type: none"> <li>Counselors who provide HCT services are involved in the processes of evaluating and improving HCT quality.</li> </ul>  |  |
| <ul style="list-style-type: none"> <li>Counselors who directly provide HCT services are required to attend regular or working meetings on HCT.</li> </ul>    |  |   |  |
| <ul style="list-style-type: none"> <li>Counselors can influence decision-making regarding HCT quality.</li> </ul>  |  |   |  |
| 6.   | Accountability of management.  | <ul style="list-style-type: none"> <li>Performance of HCT counselors is evaluated regularly (at least every six months).</li> </ul>   |  |
| <ul style="list-style-type: none"> <li>Specialists responsible for HCT quality evaluation and improvement are assigned within the administration.</li> </ul> |  |   |  |
| <ul style="list-style-type: none"> <li>Management assesses the additional training needs of HCT counselors.</li> </ul>                                       |  |   |  |
| <ul style="list-style-type: none"> <li>Management provides all HCT counselors opportunities to improve their skills and qualifications.</li> </ul>           |  |   |  |
| Notes  |  |   |  |

## Annex 4. Clinical Module

### INTRODUCTION

The Clinical Module is a guide for conducting quality assessments of health care facilities (HCF) providing clinical services to HIV-positive patients. This module is used to assess the quality and comprehensiveness of clinical services provided by HCF under programs financed by state (local) budgets, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and/or other sources.

This module is divided into ten sections:

- Facility Structure, Staffing, and Services
- Treatment and Outpatient Monitoring
- Infection Control
- Clinical HIV Prevention and Treatment Services for Pregnant Women and Their Children, and Pediatric HIV Treatment Services
- Provision of Services by Referral, and Access to Other Relevant Services
- Quality Improvement and Monitoring
- Management of Supplies of Medicines and Medical Products
- Laboratory and Other Diagnostic Services
- Client/Patient Involvement in Care, Treatment, and Support
- Health Management Information Systems

Each section begins with a list of core activity areas (competencies). This list is followed by a series of questions that can be used in discussions with representatives of the facility. Verification criteria for the core activity areas and questions are provided, along with space for making notes. Reviewers should proceed with flexibility, to accommodate the time and availability of staff for interviews.

It is assumed that reviewers will have at least six hours at each site in order to allow for completion of all sections of the tool. When the time available for an assessment is limited, reviewers should determine in advance which sections will be given top priority. For rapid visits, the bolded competencies in various sections should be addressed.

Not all sections of this tool will be applicable to all types and levels of HCF assessed. For example, some sections may apply only to Regional Centers for Prevention and Fighting AIDS (regional AIDS centers), whereas other parts may apply only to City Centers for Prevention and Fighting AIDS (city AIDS centers) and other lower-level HCFs (e.g., ART sites, Dovira/trust rooms). In such cases, the decision on which sections and questions to use will be made by the reviewer after studying available data about the HCF, and in consultation with the review team.

***Note:** Section 10 covers key issues of the Health Management Information System. However, this section should be also accompanied by a review of primary medical records. The reviewer should review a certain number of patient files (form 025/o “Outpatient Medical File” and form 030/o “Control File on Regular Medical Check-up of a HIV-positive Person”). If HCF provides services on site to fewer than 50 HIV-positive patients, 100% of patient files can be reviewed as part of the assessment. If HCF provides services to more than 50 HIV-positive patients, the expert should review at least 20% of all patient files—but no fewer than 50 primary medical records. Medical documentation is reviewed to obtain a good understanding of the level of quality of outpatient monitoring and treatment in different units of HCF, as well as within each unit. In case of lack of time for systemic review of medical data, a certain number of medical records should be reviewed in detail. The focus should be on continuity of treatment and compliance of medical care with current standards, clinical protocols, and directives of the Ministry of Health, as well as other recommendations and guidelines.*

KEY: Rapid visit Items–**Bold** | Extended visit items–All

## Section 1: FACILITY STRUCTURE, STAFFING, AND SERVICES

### Core Activity Areas (Competencies)

- **HCF provides a comprehensive range of convenient, integrated services, either on site or by referral.**
- **The number, mix, qualifications, and expertise of staff consistently meet all patient needs.**
- Operating hours, available space on the premises, and infrastructure consistently meet all patient needs, as well as the overall demand for services.
- HCF provides a full complement of services through mobile clinics, and/or expansion of patient access to services through further decentralization of medical care to raion or city and specialized HCF (e.g., psychiatric, drug treatment, and TB facilities).

### Questions

- **What services are offered for HIV prevention, care, and treatment, whether on site or by referral?**
- Do these services provided satisfy client/patient needs?
- Does selection of staff employees enable satisfaction of current needs?
- Is broad access to outpatient monitoring and treatment services ensured?

|    | <b>Performance Criteria</b>  | <b>Verification Information</b>   | <b>Comments</b> |
|----|--|---|-----------------|
| 1. | HCF provides a comprehensive range of convenient, integrated services, either on site or by referral.                                  | <i>Assessment is conducted using the Clinical Module assessment form.</i>   |                 |
| 2. | HCF and its services enable satisfaction of patient needs, as well as compliance with requirements of governing authorities/ programs. | • HCF days and hours of operation are clearly posted (using an appropriate font size) in a highly visible location.                 |                 |
|    |  | • HCF complies with all applicable sanitary and epidemiological requirements.   |                 |
|    |  | • HCF has proper spaces for counseling and examination of patients, as well as a comfortable waiting area for visitors or patients. |                 |
|    |  | • Rooms where clinical services are directly provided ensure patient confidentiality.   |                 |
|    |  | • Rooms where counseling services are provided ensure confidentiality for both visitors and patients.                               |                 |
|    |  | • Patient counseling and exam rooms comply with current sanitary norms in terms of both size and equipment.                         |                 |
|    |  | • The number of patient counseling and exam rooms meets HCF needs.  |                 |

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|    |  | <ul style="list-style-type: none"> <li>• HCF has clearly designated emergency exits.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF has fire safety equipment.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF has district or independent water supply and wastewater disposal.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF has district or independent heating.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF has district or independent electric power supply.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF is equipped with a back-up power generator.</li> </ul>  |  |
| 3. | Patients can obtain all necessary services.  | <ul style="list-style-type: none"> <li>• Operating hours of HCF specialists are clearly posted in highly visible locations that are accessible to patients and visitors.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>• Operating hours of the facility are convenient for clients/patients (e.g., before 8:00 a.m., and after 6:00 p.m., and/or on weekends and holidays).</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF has space for comfortable patient movement between rooms.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF provides free services to HIV-positive patients.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF a clinical registration desk to help patients access services.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF has required equipment to ensure easy access to clinical services for disabled patients and visitors.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>• HCF is located in an area that can be reached by public transport.</li> </ul>   |  |
| 4. | The number, expertise, qualifications, and experience of staff meet patient needs. | <ul style="list-style-type: none"> <li>• The number of personnel and the staffing mix are consistent with regulatory requirements.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>• The number of personnel and the staffing mix enable satisfaction of all client/patient needs in both clinical and non-clinical services.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>• Employees are competent in a broad range of services related to diagnosis, prevention, and treatment of HIV. They have appropriate training and education for their positions, as well as access to additional training.</li> </ul> |  |
|    |  | <ul style="list-style-type: none"> <li>– All HCF staff have basic training in prevention, diagnosis, and treatment of HIV/AIDS.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>– All providers of clinical services have advanced training in prevention, diagnosis, and treatment of HIV/AIDS.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>– HCF has qualified clinical and trained non-clinical employees providing HIV care and treatment services, in particular to children and adolescents.</li> </ul>  |  |
|    |  | <ul style="list-style-type: none"> <li>– HCF has employees trained in prevention, diagnosis, and treatment of HIV/AIDS.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>– HCF has employees trained in prevention, diagnosis, and treatment of opportunistic infections.</li> </ul>   |  |
|    |  | <ul style="list-style-type: none"> <li>– HCF has employees who are properly trained in prevention, diagnosis, and treatment of HIV in PWID.</li> </ul>   |  |

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|-------|---|--|--|
|       |   | <ul style="list-style-type: none"> <li>• For adherence and support counseling services, HCF involves trained social workers whose performance is supervised by HCF clinical workers.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• HCF involves patients who have some knowledge on prevention, diagnostics and treatment of HIV/AIDS in adherence and support counseling services; they are supervised by HCF clinical workers.</li> </ul>  |  |
| 5.    | If allowed or required at the local level, HCF delegates duties or uses common strategies, including the following: | <ul style="list-style-type: none"> <li>• Pharmacists delegate drug dispensing duties to nurses.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Nurses delegate some duties to non-professional workers or experienced patients (e.g., social workers, volunteers) within the HCF.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Nurses delegate some duties to non-professional workers or experienced patients (e.g., social workers, volunteers) outside the HCF.</li> </ul>  |  |
| 6.    | Broad access to outpatient monitoring and treatment services is ensured.  | <ul style="list-style-type: none"> <li>• HCF regularly assesses needs regarding further decentralization of HIV prevention, diagnosis, and treatment services, based on current epidemiological developments.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• ART sites are transferred to primary health care facilities pursuant to specific criteria; when necessary, they are established at specialized HCF (e.g., TB, psychiatric, drug treatment).</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Personnel who provide clinical services at external ART sites have the proper training and qualifications, and can obtain advisory support, supervision and mentorship from clinical staff at higher-level HCFs.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Clients/patients can easily access the ART site via public transport.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Patients travel no more than 10 km to get to the ART site.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Patients promptly start ART at the level appropriate for their condition and the progression of HIV, and do not face delays in initiation of treatment for any reason (e.g., shortage of ARV drugs, difficulty of ensuring the required range of diagnostic and lab services).</li> </ul> |  |
| Notes |   |  |  |

## Section 2. TREATMENT AND OUTPATIENT MONITORING

### Core Activity Areas (Competencies)

- **HCF clinical workers have appropriate training, and can obtain professional consultations, supervision, and advisory support.**
- **Patients are seen according to schedule, and are actively involved in the treatment, care, and support processes.**
- HCF administrative personnel actively use statistical and other data for monitoring service volumes.

### Questions

- **How are training needs assessed? How do employees obtain expert consultations, professional supervision, and/or advisory support?**
- **What system is in place to determine the frequency of doctor visits, and retain patients in the (ART) treatment program?**

|    | Performance Criteria  | Verification Information  | Comments |
|----|---|---|----------|
| 1. | HCF has an efficient operating system that enables decision-making on administration and provision of clinical services.                      | <ul style="list-style-type: none"> <li>• The team of clinical workers meets regularly.</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>• Minutes are recorded at meetings of the team of clinical workers.</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>• The team of clinical workers includes employees qualified in several areas.</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>• Meetings of the team of clinical workers regularly address statistical and other data for making decisions regarding administration and provision of clinical services.</li> </ul> |          |
| 2. | HCF uses an efficient procedure or system to schedule patient visits to doctors, and follow up with patients who miss scheduled appointments. | <ul style="list-style-type: none"> <li>• HCF has an efficient procedure or system in place to schedule patient visits to doctors pursuant to current clinical protocols, recommendations, and instructions.</li> </ul>      |          |
|    |   | <ul style="list-style-type: none"> <li>• What systems or approaches are used to follow up with patients who miss scheduled appointments, and when an ART patient does not show up for further treatment?</li> </ul>         |          |
|    |   | <ul style="list-style-type: none"> <li>– Sound maintenance of primary medical records and timely maintenance of reports, with information about the frequency of visits being documented.</li> </ul>                        |          |
|    |   | <ul style="list-style-type: none"> <li>– Making phone calls to follow up with patients.</li> </ul>  |          |
|    |   | <ul style="list-style-type: none"> <li>– Involvement of social workers or volunteers who work in HIV patient treatment and support.</li> </ul>  |          |
|    |   | <ul style="list-style-type: none"> <li>– PLHIV self-help groups.</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>– Involvement of those people in close contact with the ART patient who can provide support and help.</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>– Involvement of health care workers who provide in-home care and nursing (Ukrainian Red Cross).</li> </ul>  |          |
|    |   | <ul style="list-style-type: none"> <li>– Other effective measures (specify).</li> </ul>   |          |
|    |   | <ul style="list-style-type: none"> <li>• The facility has no efficient systems in place for patient follow up.</li> </ul>   |          |

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| 3.    | Use of regulatory framework and/or clinical protocols.                            | <ul style="list-style-type: none"> <li>• HCF has printed copies of the latest clinical protocols, recommendations, etc.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• The region has developed and introduced procedures for interaction between HCF in different fields, including primary health care (PHC) facilities, to ensure diagnosis, prevention, and treatment for HIV-positive patients.</li> </ul>  |  |
| 4.    | Patient visit procedures are efficient.   | <ul style="list-style-type: none"> <li>• There are documented patient flow and triage processes.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• There are specific processes and procedures in place for the following: <ul style="list-style-type: none"> <li>– Enrollment in care.</li> <li>– Initial visits by HIV-positive patients.</li> <li>– ART prescription and initiation.</li> <li>– Follow-up or refill visits.</li> <li>– Urgent care/emergency visits.</li> </ul> </li> </ul>   |  |
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| 5.    | Staff has sufficient opportunities for professional development and consultation. | <ul style="list-style-type: none"> <li>• HCF regularly conducts needs assessments for clinical and non-clinical staff (using the multi-disciplinary approach) at its training center.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Staff can obtain on-the-job internships at higher-level HCF.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Specialists from higher-level HCF conduct mentorship visits.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Advanced training is regularly conducted pursuant to the current regulatory framework.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Consultations are readily available with specialists experienced in diagnosis, prevention, and treatment of HIV: <ul style="list-style-type: none"> <li>– Directly at HCF.</li> <li>– By phone (from specialists at higher-level HCF).</li> <li>– All or most consulting doctors have Internet access at their workstations.</li> <li>– Consulting doctors have access to relevant medical literature at their workplaces.</li> <li>– The facility has no opportunity to readily obtain internal or external consultation.</li> </ul> </li> </ul> |  |
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### Section 3. INFECTION CONTROL

#### Core Activity Areas (Competencies)

- **HCF provides a safe environment for staff and patients.**
- **TB prevention interventions are prioritized.**
- Processes exist to minimize risk of infection after exposure to infectious materials.
- Staff is trained in basic infection control procedures.

#### Questions

- **What policies and procedures are used at HCF to protect staff and patients from infectious agents, and to manage those exposed to infection?**
- **What activities are promoted to reduce the risk of TB transmission at HCF?**
- How is staff trained in infection control procedures?
- How is medical waste handled?

|    | Performance Criteria   | Verification Information  | Comments |
|----|--|---|----------|
| 1. | There are written policies and procedures in place for infection control (IC). | • IC procedures are displayed, or an IC policy document is available for viewing.   |          |
|    |  | • The facility has no documentation of IC procedure or principles.  |          |
| 2. | Staff practice infection control.  | • HCF has running water for hand washing.   |          |
|    |  | • Appropriate protective gear is available:   |          |
|    |  | – Sterile gloves.   |          |
|    |  | – Special clothes (e.g., robes, surgical wear, face masks, coveralls for lab staff).  |          |
|    |  | – Face masks for patients with cough.   |          |
|    |  | – N95 masks for staff working with TB.  |          |
|    |  | – Staff follow universal precautions.   |          |
| 3. | There are procedures in place to reduce exposure of staff and patients to TB.  | • There is a written TB infection control plan in place.  |          |
|    |  | • HIV-positive patients are regularly screened for TB. <i>(Please specify the actual percentage of people screened for TB over the last 12 months, and check the number of patient files concerning TB screening)</i> |          |
|    |  | • Once TB suspects or TB patients are identified:   |          |
|    |  | – Separate wards (both outpatient and inpatient) are available at HCF.  |          |
|    |  | – Face masks are required for HCF visits, provided the visits are required and do not expose other patients to risk of infection.   |          |
|    |  | • These strategies are used to reduce the risk of TB transmission:  |          |
|    |  | – Waiting rooms and examination rooms are well-ventilated.  |          |
|    |  | – Persons with TB have free and prompt access to TB treatment.  |          |

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|       |  | <ul style="list-style-type: none"> <li>– Persons with TB receive a complete list of clinical services and treatment available at specialized HCFs, as needed.</li> </ul>                          |  |
|       |  | <ul style="list-style-type: none"> <li>• TB protection and treatment activities at HCF comply with regulations.</li> </ul>  |  |
|       |  | <ul style="list-style-type: none"> <li>• HCF does not ensure compliance with requirements for protection against TB infection.</li> </ul>   |  |
| 4.    | There are procedures in place for handling medical and non-medical waste, cutters, and sharps. | <ul style="list-style-type: none"> <li>• HCF complies with requirements and procedures for disposal of waste, cutters, and sharps.</li> </ul>   |  |
|       |  | <ul style="list-style-type: none"> <li>• There are separate waste disposal containers (for regular waste, potentially infectious waste, and cutters and sharps) in all clinical areas.</li> </ul> |  |
|       |  | <ul style="list-style-type: none"> <li>• Potential infectious waste is incinerated on site, or HCF has contracted for disposal of infectious waste, cutters, and sharps.</li> </ul>               |  |
|       |  | <ul style="list-style-type: none"> <li>• The procedures for medical and non-medical waste, cutters, and sharps is unclear.</li> </ul>   |  |
| 5.    | Post-exposure prophylaxis (PEP) is readily available.  | <ul style="list-style-type: none"> <li>• There are written procedures in place to cover exposure to blood and other potentially infectious body fluids.</li> </ul>                                |  |
|       |  | <ul style="list-style-type: none"> <li>• An excerpt from the PEP protocol is prominently displayed.</li> </ul>  |  |
|       |  | <ul style="list-style-type: none"> <li>• Access to PEP is available at all times.</li> </ul>  |  |
|       |  | <ul style="list-style-type: none"> <li>• Staff has been properly trained, and is aware of PEP policies.</li> </ul>  |  |
|       |  | <ul style="list-style-type: none"> <li>• HCF has no opportunity to provide PEP.</li> </ul>  |  |
| Notes |  |   |  |

#### **Section 4. CLINICAL HIV PREVENTION AND TREATMENT SERVICES FOR PREGNANT WOMEN AND THEIR CHILDREN, AND PEDIATRIC HIV TREATMENT SERVICES**

##### **Core Activity Areas (Competencies)**

- **HIV-positive pregnant women, their children, and HIV-positive newborns are provided with comfortable access to all relevant services (e.g., HIV counseling and testing, ART, family planning and care in cases of STI, counseling and prophylaxis focused on the specific needs of HIV-positive people, early diagnosis of HIV in children, nutrition, and childcare training).**
- Prevention-of-mother-to-child-transmission (PMTCT) services are integrated into antenatal care and other maternal, infant, and child health (MICH) services.

##### **Questions**

- **What services are available to HIV-positive or exposed pregnant women, mothers, and children?**
- How are PMTCT services integrated with other clinic (MICH) activities (e.g., pregnancy management, antenatal, and obstetric and neonatal care)?
- What clinical services are provided for HIV-positive children?
- What specific services are provided for HIV-positive adolescents?

|    | Performance Criteria   | Verification Information  | Comments |
|----|--|---|----------|
| 1. | Pregnant women and their HIV-positive/HIV-exposed infants have access to a range of high-quality services. | <ul style="list-style-type: none"> <li>• Staff has proper training in PMTCT, and in care and treatment of HIV-exposed and HIV-positive children.</li> <li>• PMTCT activities follow current clinical protocols, recommendations, and instructions.</li> <li>• Prompt, comprehensive diagnosis is ensured for pregnant women. <i>(Please specify the percentage of women in labor over the last 12 months for whom testing frequency complies with current regulations.)</i></li> <li>• Prescription of PMTCT drugs under current clinical protocols is ensured <i>(please specify the percentage of the total number pregnant women who received PMTCT drugs over the last 12 months):</i> <ul style="list-style-type: none"> <li>– Pregnant women for whom single-component zidovudin-based PMTCT drug was prescribed.</li> <li>– Pregnant women for whom three-component zidovudin-based PMTCT drug was prescribed.</li> <li>– Pregnant women for whom three-component abacavir-based PMTCT drug was prescribed.</li> <li>– Pregnant women for whom three-component tenofovir-based PMTCT drug was prescribed.</li> <li>– Pregnant women who did not receive PMTCT drugs.</li> </ul> </li> <li>• Pediatric HIV treatment and care procedures follow current clinical protocols, recommendations, and instructions.</li> <li>• Adolescent HIV treatment and care procedures follow current clinical protocols, recommendations, and instructions.</li> <li>• The following services are provided on site: <ul style="list-style-type: none"> <li>– HIV counseling and testing (HCT), including: <ul style="list-style-type: none"> <li>➤ Couples HCT.</li> <li>➤ Voluntary HCT for pregnant women.</li> <li>➤ Early HIV diagnosis of children (PCR-based HIV DNA diagnostics).</li> </ul> </li> <li>– CD4 testing.</li> <li>– ART for HIV-positive pregnant women.</li> <li>– Counseling on newborn care and feeding.</li> <li>– Providing free breast milk substitutes.</li> <li>– STI and TB screening for HIV-positive pregnant women and their other children.</li> <li>– A comprehensive range of family planning services.</li> <li>– Diagnosis, prevention, and treatment of opportunistic infections.</li> <li>– Care and treatment for HIV-positive children. <i>(Please specify the percentage of these children in the total number of patients who currently receive ART)</i></li> </ul> </li> </ul> |          |

|       |   |   |  |
|-------|---|---|--|
|       |   | – Free clotrimazole prophylaxis for children of HIV-positive women.   |  |
| 2.    | Provision of obstetric services to HIV-positive pregnant women, and prophylaxis for newborns. | <ul style="list-style-type: none"> <li>• C-section delivery. <i>(Please specify the percentage of HIV-positive women delivering via C-section over the last 12 months)</i></li> <li>• Natural delivery. <i>(Please specify the percentage of HIV-positive women delivering vaginally over the last 12 months)</i></li> </ul>  |  |
| 3     | PMTCT is integrated into other maternal, infant, and child health services.                   | <ul style="list-style-type: none"> <li>• Antenatal care and PMTCT services are integrated or provided at the same time by HCF staff,</li> <li>• Staff are trained in several fields: PMTCT, care of HIV-positive adults and children.</li> <li>• Payroll includes a pediatrician or children’s infection specialist.</li> <li>• HCF designates specific clinic days for children.</li> <li>• HIV-positive children and mothers receive clinical services at specialized HCF, as well as at PHC providers.</li> <li>• Scheduled vaccinations can be given either at specialized HCF or at PHC providers.</li> <li>• Initiation of free clotrimazole prophylaxis follows current protocol.</li> </ul> |  |
| 4     | There is linkage among various services.  | <ul style="list-style-type: none"> <li>• Services by referral are provided and tracked.</li> <li>• Social workers (volunteers) are involved in the process of tracking mothers and their children for social support services.</li> </ul>   |  |
| 5     | Age-appropriate HIV services are available for children.                                      | <ul style="list-style-type: none"> <li>• Pediatric counseling and patient age-appropriate disclosure of HIV status are provided.</li> <li>• Services for HIV-positive adolescents are provided separately.</li> <li>• HIV-positive children are counseled on disclosure and acceptance of diagnosis.</li> </ul>   |  |
| Notes |   |   |  |

## Section 5. PROVISION OF SERVICES BY REFERRAL, AND ACCESS TO OTHER RELEVANT SERVICES

### Core Activity Areas (Competencies)

- HCF has written agreements, or approved plans of action, with other HCFs for services it is unable to provide itself.
- Services by referral are properly documented; results of clinical services received by referred clients are tracked.

### Questions

- What formal linkages does HCF maintain with other HCFs for those clinical services it can provide only by referral? How do PLHIV access these services?
- What systems are currently used to document and monitor referrals to other services, as well as feedback from other HCFs?

|       | <b>Performance Criteria</b>   | <b>Verification Information</b>   | <b>Comments</b> |
|-------|---|---|-----------------|
| 1.    | The referral process is standardized and systematic.  | <ul style="list-style-type: none"> <li>• A standard authorized referral form is used.</li> <li>• State-approved forms are used for referrals.</li> <li>• Referrals are recorded and tracked.</li> </ul>   |                 |
| 2.    | A system is in place for sharing information and feedback among HCFs for services by referral.                      | <ul style="list-style-type: none"> <li>• Feedback from HCF that provides services by referral is tracked.</li> <li>• Referral logs are used.</li> </ul>   |                 |
| 3.    | At NGOs that have cooperative agreements with HCF, an HIV-positive patient can obtain relevant services, including: | <ul style="list-style-type: none"> <li>• TB diagnostics using costly methods (e.g., computed tomography (CT) scan, magnetic resonance tomography/imaging (MRT/MRI)).</li> <li>• Parenteral nutrition services in intensive care units.</li> <li>• Social and psychosocial support services.</li> <li>• Palliative and in-home hospice care, including the use of drugs and anesthetics (Ukrainian Red Cross).</li> <li>• Patronage and in-home care services.</li> <li>• PLHIV peer support groups.</li> <li>• Other services (specify).</li> </ul> |                 |
| Notes |   |   |                 |

## Section 6. QUALITY IMPROVEMENT AND MONITORING

### Core Activity Areas (Competencies)

- **HCF has implemented a quality assurance and assessment process for clinical services.**
- HCF has set key performance indicators, and uses them to assess activities and improve patient care.

### Questions

- **What is the process for assessing quality of medical care, and identifying and addressing service delivery problems at HCF? Which specialists are involved in this process?**
- **How are statistical and other data describing HCF activity used to assess and improve the quality of clinical services?**

|    | <b>Performance Criteria</b>   | <b>Verification Information</b>  | <b>Comments</b> |
|----|---|--|-----------------|
| 1. | HCF has a quality improvement process in place for clinical services. | <ul style="list-style-type: none"> <li>• A team of qualified specialists has been assigned responsibility for medical care assessment and quality improvement.</li> <li>• A written plan for medical care assessment and quality improvement has been developed.</li> <li>• A report on medical care assessment and quality improvement activities taken in the last year at HCF is available for viewing.</li> <li>• Minutes are taken at meetings of specialists responsible for medical care assessment and quality improvement.</li> </ul> |                 |

|       |  |   |  |
|-------|--|---|--|
|       |  | <ul style="list-style-type: none"> <li>• These quality improvement activities are documented: <ul style="list-style-type: none"> <li>– Review of patient medical records (Form 025/o) and checklists (Form 030/o).</li> <li>– Analysis of data on patient retention in care.</li> <li>– Meetings on reason analysis of patient deaths.</li> </ul> </li> </ul>   |  |
| 2.    | HCF has set clinical performance indicators and targets, and they are regularly monitored. HCF met its targets (indicators) last year. | <ul style="list-style-type: none"> <li>• Indicators have been set, and are prominently displayed.</li> <li>• Indicators are monitored on a regular basis, using the appropriate reporting forms.</li> <li>• The facility met its targets (indicators) last year for the following fields of activity: <ul style="list-style-type: none"> <li>– HIV testing: <ul style="list-style-type: none"> <li>➤ Total number of persons tested.</li> <li>➤ The number of members of at-risk groups.</li> <li>➤ The number of tests performed by request of health care providers.</li> <li>➤ Coverage of pregnant women and their partners.</li> </ul> </li> <li>– Coverage of HIV-positive people through outpatient monitoring and treatment. (The active outpatient monitoring group consists of the total number of patients who receive clinical services, the number of new patients diagnosed with HIV in the running year, and the total number of current patients).</li> <li>– Coverage of patients through ART (the number of people receiving ART, and the percentage of the total number of HIV-positive people in need of ART).</li> <li>– Retention of patients in the ART program (the cohort of patients who started treatment).</li> <li>– Care of HIV-positive children. (The active outpatient monitoring group consists of the total number of patients who receive clinical services, the number of new patients diagnosed with HIV in the running year, and the total number of current patients.)</li> <li>– Children receiving ART (the number of patients receiving ART, and the percentage of the total number of HIV-positive people in need of ART—to ensure 100% coverage of HIV-positive children in need of treatment).</li> <li>– Provision of TB diagnostic, prevention, and treatment services (the number of patients who received TB diagnosis, prevention, and treatment services). <i>(Please specify separately the number of patients who received treatment of HIV and TB simultaneously, and the percentage of HIV-positive people having first been diagnosed with TB).</i></li> <li>– Ensuring regular drug refill visits by patients (the number of patients who failed to regularly visit HCF for prescription refills, and the percentage of the total number of patients on ART).</li> <li>– Other HCF performance indicators (specify).</li> </ul> </li> </ul> |  |
| Notes |  |   |  |

## Section 7. MANAGEMENT OF SUPPLIES OF MEDICINES AND MEDICAL PRODUCTS

### Core Activity Areas (Competencies)

- HCF has monitoring systems in place to ensure continuous availability of medications for all HIV services (e.g., ART, control of opportunistic infections, palliative care).
- Patients who take medications are given adequate information about the importance of uninterrupted treatment, and compliance with schedules of drug administration and prescription instructions; in addition, patient adherence to treatment is monitored.
- A process is in place to eliminate drug dispensing errors, and to track cases in which a patient has failed to receive medications in a timely manner.

### Questions

- **What systems are in place at HCF to ensure sufficient stocks and uninterrupted supply of medications, laboratory reagents, and other consumables?**
- How many shortages of ARV drugs, laboratory reagents, and drugs for treating opportunistic infections were there over the last 12 months? Please specify duration and cause(s) for each case.
- What systems are in place at HCF to dispose of expired drugs?
- How is patient motivation to maintain treatment assessed? How is adherence to treatment ensured?

|  | Performance Criteria  | Verification Information  | Comments                                    |   |  |
|--|---|---|---|---|--|
| 1.   | There is an efficient supply system in place for medications and commodities. | <ul style="list-style-type: none"> <li>• Supplies of medications and medical products are:               <ul style="list-style-type: none"> <li>– Handled within the public procurement and supply system.</li> <li>– Organized by HCF out of local budget funds, as part of a procurement and supply system.</li> <li>– Handled within a procurement and supply system out of donor funds (humanitarian aid).</li> </ul> </li> </ul> |   |   |  |
|  |   | • Inventory is separated by supply sources.   |   |   |  |
|  |   | • Data on receipt and use of medications is collected, both electronically and in hard-copy form.   |   |   |  |
|  |   | • Inventory monitoring is continuously updated.   |   |   |  |
|  |   | • An efficient system of inventory forecasting is in place.   |   |   |  |
|  |   | • An efficient system of ordering is in place   |   |   |  |
|  |   | • There is sufficient inventory of ARV drugs to cover at least two months.  |   |   |  |
|  |   | 2.  | Medications are stored securely and safely. | <ul style="list-style-type: none"> <li>• HCF has designated secured-storage areas (e.g., warehouse, pharmacy point, and drug dispensing points).</li> </ul> |  |
|  |   |   |   | <ul style="list-style-type: none"> <li>• Drugs are stored in temperature- and humidity-controlled environments.</li> </ul>                                  |  |
| <ul style="list-style-type: none"> <li>• Temperature at storage facilities is documented using the appropriate forms.</li> </ul>       |   |   |   |   |  |
| <ul style="list-style-type: none"> <li>• There are no expired drugs on the shelves.</li> </ul>   |   |   |   |   |  |
| <ul style="list-style-type: none"> <li>• There is a record of expired drugs and their disposal.</li> </ul>                             |   |   |   |   |  |
| <ul style="list-style-type: none"> <li>• There is a process in place to first dispense drugs with shorter expiration dates.</li> </ul> |   |   |   |   |  |

|    |   |   |  |
|----|---|---|--|
|    |   | <ul style="list-style-type: none"> <li>Pharmacist(s), administrative staff, and other persons (please specify) have keys to the warehouse or pharmacy points.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>A dedicated pharmacist or legally certified dispenser is present during regular operating hours.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>Only pharmacists and other legally certified staff authorized by HCF may dispense medications.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>Methods are used to minimize errors in prescription and dispensation (e.g., pre-printed prescriptions, verification of changes in prescriptions, electronic dispensing tools).</li> </ul>                              |  |
| 3. | Patients are given adequate information about their medications.  | <ul style="list-style-type: none"> <li>Patients are counseled on how to store and administer drugs, how to minimize potential side effects, and how to safely discontinue ART.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>Separate procedures are in place for patients initiating ART, and those needing drug refills.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>Records are kept, either electronically or in hard-copy form, concerning who gets what medications.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>Adherence counseling is provided at the pharmacy.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>Adherence is regularly monitored by the dispenser, either through pill counts or patient self-reports.</li> </ul>  |  |
| 4. | Receipt, flow, and use of medications and milk formulas are documented.   | <ul style="list-style-type: none"> <li>Medication delivery notes are stored according to financing sources.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>Maintenance of prescription drug logs is in compliance with current regulations.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>Drugs dispensed to patients are properly logged.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>HCF has introduced a mechanism for documenting transfers of medications to other HCFs that provide clinical services to HIV-positive patients.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>Accuracy of recordkeeping and reporting (both electronically and in hard-copy form) on dispensing of medications at decentralized ART sites is ensured.</li> </ul>   |  |
|    |   | <ul style="list-style-type: none"> <li>All specialists involved in receipt, storage, and transfer of medications are appropriately trained on monitoring and documentation of prescription drug flow, and rules of receipt, transfer, and storage.</li> </ul> |  |
| 5. | There is an efficient supply chain system in place for medications and milk formulas; inventory is safely and securely stored at HCF. | <ul style="list-style-type: none"> <li>Supply stocks are regularly monitored.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>An efficient system for ordering medications and medical products is in place.</li> </ul>  |  |
|    |   | <ul style="list-style-type: none"> <li>In cases of emergency, alternative ordering procedures, including reallocation of drug supplies to/from other HCFs, are implemented to replenish drugs, medical products, and milk formula stocks.</li> </ul>          |  |
|    |   | <ul style="list-style-type: none"> <li>For medications, medical products, and milk formulas purchased locally, an efficient purchase and supply process is in place to allow for regular delivery of supplies in accordance with actual need.</li> </ul>      |  |
|    |   | <ul style="list-style-type: none"> <li>There are designated secure facilities on site for storage of medications and milk formulas.</li> </ul>  |  |

|       |  |  |  |
|-------|--|--|--|
|       |  | <ul style="list-style-type: none"> <li>HCF staff involved in inventory monitoring and drug needs planning are duly trained on the above issues.</li> </ul>   |  |
| 6.    | There were no recorded shortages of ARV drugs, medications for treatment of opportunistic infections, milk formulas, or laboratory reagents in the last 12 months. | <ul style="list-style-type: none"> <li>In the last 12 months, were there shortages of ARV drugs? If so, which ARV drugs? How often did such shortages happen? How long did each specific case last?</li> </ul>   |  |
|       |  | <ul style="list-style-type: none"> <li>In the last 12 months, were there shortages of medications for treatment of opportunistic infections? If so, which medications? How often did such shortages happen? How long did each specific case last?</li> </ul> |  |
|       |  | <ul style="list-style-type: none"> <li>In the last 12 months, were there shortages of laboratory reagents? If so, which reagents? How often did such shortages happen? How long did each specific case last?</li> </ul>                                      |  |
|       |  | <ul style="list-style-type: none"> <li>In the last 12 months, were there shortages of milk formulas? If so, how often did such shortages happen? How long did each specific case last?</li> </ul>  |  |
| Notes |  |  |  |

## Section 8. LABORATORY AND OTHER DIAGNOSTIC SERVICES

### Core Activity Areas (Competencies)

- **Patients have access to essential laboratory tests and other diagnostic services, either on site or through referrals to other HCF.**
- **Staff numbers and skills, laboratory space, equipment, and reagents meet HCF needs at all times.**
- Contracts for equipment maintenance and support or repair entered into by HCF are in effect.
- Standard operating procedure (SOP) documentation is available for relevant lab tests.
- Tests, and their appropriate controls, are conducted according to SOPs.
- A cold chain for reagents is ensured.

### Questions

- **What HIV-related laboratory tests and diagnostics are conducted on site? How are they integrated into HCF lab services?**
- What procedures are in place to ensure accurate/high-quality results? (Please explore the following: SOP, preparation, quality control, equipment service contracts, information systems.)
- What systems are in place to ensure that equipment is regularly maintained?
- What processes are in place to ensure that a cold chain for reagents is constantly maintained?

|    | Performance Criteria   | Verification Information   | Comments |
|----|--|--|----------|
| 1. | Laboratory tests are performed reliably, results are accurately recorded, and client/patient | <ul style="list-style-type: none"> <li>SOPs are prominently displayed, and followed for all tests conducted on site</li> </ul>           |          |
|    |  | <ul style="list-style-type: none"> <li>Lab staff conducting tests have appropriate training.</li> </ul>                                  |          |
|    |  | <ul style="list-style-type: none"> <li>Lab staff have access to reagents and controls needed for all tests performed on site.</li> </ul> |          |
|    |  | <ul style="list-style-type: none"> <li>Testing platforms used on site are included on the</li> </ul>                                     |          |

|       |   |  |  |
|-------|---|--|--|
|       | confidentiality is ensured.   | list of state-approved procedures.   |  |
|       |   | <ul style="list-style-type: none"> <li>• Testing platforms used on site meet local needs (e.g., throughput, turnaround time, staff hours and skill levels, space and supply requirements).</li> </ul>            |  |
|       |   | <ul style="list-style-type: none"> <li>• An information system is in place to ensure patient confidentiality and accurate reporting of results.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Lab results are sent to health care providers in a timely fashion.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Specified procedures are used for urgent testing.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Processes are in place to expedite reporting of critical results.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• The laboratory has a reliable electrical power supply.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• The laboratory has a reliable water supply and wastewater disposal system (with free access to sterile water, where specified).</li> </ul>                              |  |
|       |   | <ul style="list-style-type: none"> <li>• A cold chain is maintained for all reagents.</li> </ul>   |  |
| 2.    | Patients have access to an extensive range of laboratory services.  | <i>Assessment is conducted using the Clinical Module assessment form.</i>  |  |
| 3.    | The laboratory is regularly inspected, equipment maintained and calibrated, and processes are in place to ensure quality testing. | <ul style="list-style-type: none"> <li>• An external quality assurance (EQA) report is available for viewing.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• EQA and proficiency testing were conducted during the past year. Results of EQA actions provide evidence of the quality of HCF services.</li> </ul>                     |  |
|       |   | <ul style="list-style-type: none"> <li>• Available documentation contains up-to-date information on schedules for inspection, testing, calibration, and maintenance of equipment, including droppers.</li> </ul> |  |
|       |   | <ul style="list-style-type: none"> <li>• Documentation of internal quality assurance (QA) and control (QC) procedures is available for viewing.</li> </ul>   |  |
| 4.    | Patients can obtain other diagnostic services (e.g., x-ray, ultrasound).  | <ul style="list-style-type: none"> <li>• HCF has all necessary diagnostic equipment to provide comprehensive care on site.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Equipment is properly maintained.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Qualified, properly trained staff are responsible for maintenance of x-ray and other diagnostic equipment.</li> </ul>   |  |
|       |   | <i>A detailed assessment covering required diagnostic equipment should be provided using the assessment form found as an appendix to the Clinical Module (Section 1).</i>  |  |
| Notes |   |  |  |

## Section 9. CLIENT/PATIENT INVOLVEMENT IN CARE, TREATMENT, AND SUPPORT

### Core Activity Areas (Competencies)

- **HCF conducts training in outpatient monitoring, care, and support for patients.**
- Clients/patients are empowered to become active participants in management of their care.
- The organization/facility gathers and uses feedback (comments) from patients and the community regarding medical care needs.

### Questions

- **What training in outpatient monitoring, care, and support are conducted for patients? By whom? How?**
- How are clients/patients able to communicate their comments, wishes, and requirements concerning quality of clinical services?
- How does HCF actively engage PLHIV in the process of decision-making regarding patient care and treatment?

|    | Performance Criteria   | Verification Information   | Comments |
|----|--|--|----------|
| 1. | HCF assesses how well patients understand their condition, and their medical, social, and psychological needs. | Patient understanding and acceptance of their condition is documented in primary medical records (Form 025/o).   |          |
| 2. | Care and treatment education is provided.  | • Information on posters and other reading materials is printed in plain language.   |          |
|    |  | • Information about training sessions conducted in care and treatment is recorded in primary medical records, and includes dates, session subjects, methodology, tutors, etc.        |          |
|    |  | • Care and treatment education sessions are conducted for individuals and groups.  |          |
|    |  | • After each session, the understanding of PLHIV of their health condition is assessed and documented.   |          |
| 3. | Informed consent of the patient is obtained for major care and treatment decisions.                            | • HCF observes proper procedure for obtaining informed consent from the patient for ART initiation.  |          |
|    |  | • HCF observes proper procedure for obtaining informed consent from the patient for diagnosis and treatment, and surgeries and analgesia (form 003-6/o).                             |          |
| 4. | Patients have opportunities to contribute to decisions regarding the services they obtain.                     | • HCF has developed a questionnaire to obtain information about the level of patient satisfaction with clinical services received.   |          |
|    |  | • HCF stores completed patient questionnaires.   |          |
|    |  | • HCF has suggestion boxes in place; opinions and suggestions received are analyzed, and taken into consideration when making decisions regarding improvements to clinical services. |          |
|    |  | • Patients are actively enrolled in self-support groups.   |          |
|    |  | • Support groups are age- and/or gender-specific, and available for certain at-risk groups (e.g., PWID, MSM).  |          |

|       |  |   |  |
|-------|--|---|--|
| 5.    | Gender equality in care and treatment is promoted. | <ul style="list-style-type: none"> <li>• Women and men have equal access to HIV services at HCF.</li> </ul>   |  |
|       |  | <ul style="list-style-type: none"> <li>• HIV-positive women have access to support groups at HCF.</li> </ul>  |  |
|       |  | <ul style="list-style-type: none"> <li>• HCF engages specialists (e.g., volunteers, social workers, attorneys, and psychologists) to provide domestic-abuse counseling and assistance to HIV-positive women.</li> </ul>                                     |  |
|       |  | <ul style="list-style-type: none"> <li>• Information on competent services that provide assistance to women, children, and adolescents on domestic abuse and other kinds of violence, including sexual assault, are prominently displayed in HCF</li> </ul> |  |
| Notes |  |   |  |

## Section 10. HEALTH MANAGEMENT INFORMATION SYSTEMS

### Core Activity Areas (Competencies)

- **HCF uses a universal information system to maintain primary medical records and reports.**
- **The information system introduced as part of routine practice at HCF helps generate ongoing reports that enable assessment of HCF performance.**
- **The information system ensures confidentiality, security, and accuracy of patient data.**
- Personal patient data is stored in an appropriately organized manner, and ensures confidentiality.
- Clinical staff working with the information system have completed proper training.

### Questions

- **What information system is used to collect, compile, and report medical data?**
- **What processes are used to ensure data verification and correction?**
- Does the information system enable accurate evaluation of performance of HCF and its systems, as well as consolidation of reports?
- How flexible is the information system? Can it be adapted to new data collection methods, changing data, and new reporting needs?
- Do the number of staff, their skills, and the information system make it possible to satisfy HCF needs?

|    | Performance Criteria                                     | Verification Information  | Comments |
|----|--|---|----------|
| 1. | A unified medical records system is in place.            | The HCF medical documentation management system:  |          |
|    |  | <ul style="list-style-type: none"> <li>• A paper-based (hard-copy) or electronic medical record system is in use.</li> </ul>  |          |
|    |  | <ul style="list-style-type: none"> <li>• Maintenance of primary records and reports complies with current regulations.</li> </ul>   |          |
| 2. | Patient medical records are standardized and structured. | <ul style="list-style-type: none"> <li>• Designated standardized forms for records and reports are used to maintain treatment and care records, and to collect data.</li> </ul> |          |
|    |  | <ul style="list-style-type: none"> <li>• Each patient record is marked with a unique identifier and/or the patient's name.</li> </ul>   |          |

|       |   |  |  |
|-------|---|--|--|
| 3.    | Records are systematically filed and safely stored.   | <ul style="list-style-type: none"> <li>• Paper-based (hard-copy) documents are stored: <ul style="list-style-type: none"> <li>– in lockable offices.</li> <li>– in lockable rooms with restricted access.</li> <li>– Designated records officer(s) (recordkeepers) are responsible for storage and filing of original medical records.</li> </ul> </li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Electronic documents: <ul style="list-style-type: none"> <li>– The information system servers containing patient information are housed in a lockable room with restricted access.</li> <li>– User passwords are required for access.</li> <li>– Data is regularly backed up or copied.</li> <li>– Backups are securely stored.</li> <li>– A designated person is responsible for data storage and security.</li> </ul> </li> </ul> |  |
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|       |   |  |  |
| 4.    | Medical record flows are organized.   | HCF has a system for the following:  |  |
|       |   | <ul style="list-style-type: none"> <li>• HCF ensures that the archived documents of inactive patients (e.g., those who have died, were transferred to another HCF, or lost to follow-up) are stored separately from documents of active patients.</li> <li>• A mechanism is in place for tracking documents issued within HCF during patient visits.</li> </ul>  |  |
| 5.    | Medical documents are checked for completeness and accuracy.  | Medical documents are checked:   |  |
|       |   | <ul style="list-style-type: none"> <li>• All documents (records and reports) that are maintained electronically and on paper indicate when services were delivered and reports generated and submitted.</li> <li>• Maintenance of primary records and reports is monitored for accuracy.</li> </ul>  |  |
| 6.    | Information contained in patient-level electronic databases or tools is up-to-date, accurate, protected, and actively used. | <ul style="list-style-type: none"> <li>• HCF obtains informed consent, in the form of patient signatures, for personal data processing.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• The written consent for personal data processing is stored pursuant to current laws.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Registration of any personal information database conforms to current regulations.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• HCF's patient database is fully certified, and HCF has obtained all appropriate permits.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Electronic patient database is regularly updated. All patient documents are complete.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Data stored in databases is accurate and fully corresponds with hard-copy data.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• Database maintenance staff are properly trained.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Employees who work with data are trained to generate and prepare reports according to predetermined criteria.</li> </ul>  |  |
|       |   | <ul style="list-style-type: none"> <li>• The database is regularly backed up; backups are securely stored in a separate location.</li> </ul>   |  |
|       |   | <ul style="list-style-type: none"> <li>• Only encrypted or anonymized patient-level data is transferred outside the facility.</li> <li>• If the database is used for research, all appropriate ethical clearances should be obtained.</li> </ul>   |  |
| Notes |   |  |  |

**Annex 5. List of Certified Ukrainian Reviewers  
and Regional Coordinators for CIASS Assessments**

| <b>Full Name and Email</b>                  | <b>Position and Workplace</b>   | <b>Module</b>  | <b>Regions Coordinated</b>  |
|---|---|----------------|---|
| Ihor Kuzin<br>i.kuzin@ukraids.gov.ua        | Head of the Center for Monitoring and Evaluation of Programmatic HIV/AIDS Response Activities<br>SI “Ukrainian Center for Socially Dangerous Disease Control under the Ministry of Health of Ukraine” | Administrative | Any region, national-level institutions   |
| Vira Yatsyk<br>yatsyk@ukraids.gov.ua        | Specialist in development of the regional monitoring and evaluation system<br>SI “Ukrainian Center for Socially Dangerous Disease Control under the MOH of Ukraine”                                   | Administrative | Any region  |
| Serhiy Riabokon<br>rskva@ukr.net            | Specialist in HIV/AIDS treatment analysis<br>SI “Ukrainian Center for Socially Dangerous Disease Control under the MOH of Ukraine”  | Clinical       | Any region  |
| Nataliia Kovbasiuk<br>taliako2013@gmail.com | Consultant<br>SI “Ukrainian Center for Socially Dangerous Disease Control under the MOH of Ukraine”   | Financial      | Oblasts:<br>Dnipropetrovsk, Odessa, Donetsk, Mykolayiv, Kherson, Chernihiv<br>Autonomous Republic of Crimea, City of Sebastopol, City of Kyiv |
| Olena Velyhodska<br>p_aids_zp@mail.ru       | Head of the Monitoring and Evaluation Center<br>Municipal Enterprise<br>“Zaporizhzhia Oblast AIDS Center”   | Administrative | Oblasts:<br>Kyiv, Cherkasy, Zaporizhzhia, Luhansk, Zhytomyr, Kirovohrad, Poltava, Volyn, Khmelnytskyi   |
| Oksana Kutynska<br>mio.lviv@gmail.com       | Head of the Monitoring and Evaluation Center<br>Communal Institution<br>“Lviv Oblast AIDS Center”   | Administrative | Oblasts:<br>Vinnytsia, Rivne, Kharkiv, Lviv, Sumy, Chernivtsi, Ternopil, Ivano-Frankivsk, Zakarpattia   |

|   |  |                            |  |
|---|--|----------------------------|--|
| Zhanna Antonenko<br>zhana.antonenko@gmail.com | Head of the Monitoring and Evaluation Center<br>Kyiv City AIDS Center at Kyiv City Clinical Hospital #5  | Administrative             | Oblasts:<br>Dnipropetrovsk, Odessa, Donetsk, Mykolayiv, Kherson, Chernihiv Autonomous Republic of Crimea, City of Sebastopol, City of Kyiv |
| Hanna Lopatenko<br>Lopatenko.anna@gmail.com   | Head of the Monitoring and Evaluation Center<br>Communal Institution “Dnipropetrovsk Oblast AIDS Center” | HIV Counseling and Testing | Oblasts:<br>Vinnytsia, Rivne, Kharkiv, Lviv, Sumy, Chernivtsi, Ternopil, Ivano-Frankivsk, Zakarpattia                                      |
| Iryna Soroka<br>sorokair@ukr.net              | Head of the Monitoring and Evaluation Center<br>“Odessa Oblast AIDS Center”                              | Clinical                   | Oblasts:<br>Dnipropetrovsk, Odessa, Donetsk, Mykolayiv, Kherson, Chernihiv Autonomous Republic of Crimea, City of Sebastopol, City of Lviv |
| Nadiia Prokopenko<br>prokopenkoua@ukr.net     | Head of the Outpatient Department<br>Municipal Institution “Cherkasy Oblast AIDS Center”                 | Clinical                   | Oblasts:<br>Kyiv, Cherkasy, Zaporizhzhia, Luhansk, Zhytomyr, Kirovohrad, Poltava, Khmelnytskyi, Volyn                                      |
| Yuliia Kvasnevska<br>y.kvasnevska@gmail.com   | ANTIAIDS Foundation (USA) in Ukraine   | HIV Counseling and Testing | Oblasts:<br>Kyiv, Cherkasy, Zaporizhzhia, Luhansk, Zhytomyr, Kirovohrad, Poltava, Khmelnytskyi, Volyn                                      |

## **Annex 6. Principal Responsibilities and Qualification Requirements for CIASS Assessment Technique Experts**

An assessment should involve specialists from health care facilities who are properly trained, and possess a CIASS assessment expert certificate for at least one of the respective modules.

In some cases, training and certification of experts who are not specialists of health care facilities is considered.

Training and certification of CIASS assessment experts shall be provided by SI “Ukrainian Center for Socially Dangerous Disease Control under the MOH of Ukraine” (UCSDDC) as the principal coordinator of CIASS activities in Ukraine.

The number of team members depends on the level and range of services offered by the facility under assessment.

The team of experts usually includes reviewers for all areas, namely:

- Administration
- Finance
- HIV Counseling and Testing (HCT)
- Clinical Services

An assessment must include the Administrative and Financial Modules. Participation of experts in the Clinical and HCT Modules depends on the activities of the facility and the services it provides.

Whenever possible, the expert team should include at least one expert representing the UCSDDC.

Where necessary, two experts in the same area can take part in an assessment.

### **Assessment Team Lead**

A nominee for the assessment team lead shall be designated at the preparatory stage by the regional coordinator, subject to clearance by the UCSDDC.

The team lead shall have authority to speak on behalf of the whole team of experts at all stages of assessment preparation and implementation. The team lead shall be responsible for overall coordination of the activities of the assessment team, and in particular perform the following duties:

- Organize and hold meetings between members of the assessment team and the staff of the facility under assessment.
- Supervise implementation of an assessment plan and its timeline.
- Set limits for responsibility and coordination of activities.
- Prevent and manage conflict situations that may arise while performing an assessment.
- Organize and conduct internal meetings of assessment team members upon completion of each stage of the assessment.
- Coordinate preparation and presentation of findings as part of a debriefing session.
- Coordinate activities of all team members to prepare assessment reports.

The assessment team lead may combine these activities with performance of assessment duties in one of the areas.

### **Clinical Module Team Member**

Wherever possible, assessment under the Clinical Module should involve a physician who has expertise in treatment of HIV-positive patients, or a specialist in the field of management and/or administration of health care facilities who has treatment and administration expertise from institutions providing clinical services to HIV-positive patients, or is experienced in the support and implementation of HIV prevention and treatment programs in government bodies and/or international organizations.

### **Administrative Module Team Member**

Ideally, assessment under the Administrative Module should involve a specialist in public health, an expert in the field of management and/or administration of health care facilities, or an NGO expert, including someone from an international NGOs who has expertise in treatment and administration at institutions providing clinical services to HIV-positive patients, or is experienced in the support and implementation of HIV prevention and treatment programs in government bodies and/or international organizations.

### **HCT Module Team Member**

Ideally, assessment under the HCT Module should involve a specialist with medical, pedagogical, sociological, psychological, public health, and/or management education, and/or experience in administration of health care facilities, who has expertise in the organization, support, and implementation of HCT programs in institutions of all levels and ownership patterns.

### **A Financial Module team member**

Ideally, assessment under the Financial Module should involve a specialist with education in economics, and relevant expertise in the field of financial management of health care facilities and/or NGOs, including international NGOs.

**Annex 7. Sample Letter to the Regional Coordinator  
Requesting a CLASS Assessment**

The letter shall be sent using the official letterhead of the entity.

Dear \_\_\_\_\_:

The state institution / facility \_\_\_\_\_ assures you of its considerations and informs as follows.

With the objective of performing a qualitative assessment of the facility and identifying its successes and capabilities, assessing its needs in capacity strengthening, and seeking out ways and resources to ensure a sustainable, continuous process for providing quality services, you are kindly asked to conduct a Clinical Assessment for Systems Strengthening (CLASS) at the following facility (facilities): \_\_\_\_\_ – to further strengthen its (their) capacity and assure sustainability in implementation of the program.

If you have any questions related to organization of the assessment, please feel free to contact \_\_\_\_\_, phone number \_\_\_\_\_.

Regards,

Director of the facility \_\_\_\_\_

## Annex 8. Sample Letter Addressing the Facility to Be Assessed

The letter shall be sent using the official letterhead of the entity.

Dear \_\_\_\_\_:

The state institution / facility \_\_\_\_\_ assures you of its considerations and informs as follows.

With the objective of performing a qualitative assessment of the facility and identifying its successes and capabilities, assessing its needs in capacity strengthening, and seeking out ways and resources to ensure a sustainable, continuous process for providing quality services, we propose conducting a Clinical Assessment for Systems Strengthening (CLASS) at the following facility (facilities): \_\_\_\_\_ – to further strengthen its (their) capacity and assure sustainability in implementation of the program.

If you have any questions related to organization of the assessment, please feel free to contact \_\_\_\_\_, phone number \_\_\_\_\_.

Please provide us with a letter of support and consent for the assessment.

Regards,

Director of the facility \_\_\_\_\_

## **Annex 9. List of Facility Documents to Be Reviewed Before a CLASS Assessment Site Visit**

### **For state-owned facilities:**

- A current copy of the facility's annual plan, including its plans for monitoring/mentorship visits to lower-level facilities.
- The most recent annual report on fulfillment of activities under the regional HIV/AIDS target program.
- The staffing schedule (include both staffed and vacant positions).
- Principal reporting documents (for health care facilities: periodic reports, in compliance with current directives of the Ministry of Health of Ukraine).
- Copies of statutory documents.

### **For NGOs:**

- A copy of the most recent order authorizing the facility to provide HIV services.
- Reports for donor organization monitoring visits.
- NGO responses to the findings of the donor organization's monitoring visits.

**Annex 10. Sample Brief to Be Sent to the Facility  
at the Assessment Preparation Stage**

|   |   |  |
|---|---|--|
| 1 | Location                                | <p><i>Name of the administrative territorial unit</i><br/> <i>Name of the institution (institutions) to be assessed</i><br/> <i>An action planning session:</i><br/> <i>Location:</i></p>  |
| 2 | Tentative dates and times               | <p><i>Facility No. 1</i><br/> <i>Dates: from ____ to ____ (day, month, year)</i><br/> <i>Time: from ____ to ____ (hour, min.)</i><br/> <i>Facility No. 2</i><br/> <i>Dates: from ____ to ____ (day, month, year).</i><br/> <i>Time: from ____ to ____ (hour, min.)</i><br/> <i>Facility No. 3, etc.</i><br/> <i>An action planning session</i><br/> <i>Date: (day, month, year)</i><br/> <i>Time: from ____ to ____ (hour, min.)</i></p>   |
| 3 | Team of experts                         | <p>Expert team lead<br/> ____ Module expert _____ (full name)<br/> ____ Module expert _____ (full name)<br/> ____ Module expert _____ (full name)<br/> ____ Module expert _____ (full name)</p>  |
| 4 | Goal of the assessment                  | <p>The goal of the team’s visit is to explore best practices, areas for improvement, and the needs of the facility under assessment in order to strengthen the system of available treatment, care, and support services for PLHIV and their scale-up. Special attention should be paid to the following:</p> <ul style="list-style-type: none"> <li>• Efficient use and management of available resources.</li> <li>• Program management and administration.</li> <li>• Securing financial stability.</li> <li>• Strengthening human resources and managerial capacity.</li> <li>• Ensuring comprehensive, quality clinical and HCT services provided by the facility.</li> </ul>   |
| 5 | Assessment technique and key objectives | <p>CIASS (Clinical Assessment for Systems Strengthening) is a technique for qualitative assessment of facility operations. It is intended to identify the participating organization’s capabilities and capacity-building needs. Unlike traditional approaches, <b>a CIASS assessment is not an audit</b>, as the assessment process involves not only the team of experts conducting the assessment, but also representatives of the facility being assessed; it aims not only to identify a facility’s areas for improvement, but also to find ways to overcome them.</p> <p>The key objective of a CIASS assessment is to seek out ways and resources to ensure a sustainable, continuous process for providing quality services.</p> <p>The specific objectives of a CIASS assessment are:</p> <ul style="list-style-type: none"> <li>• Analysis of the administrative, financial, and technical capacities of the facility implementing HIV treatment, care, and support programs.</li> <li>• Developing a plan of action to improve the facility’s operations and resolve problems identified.</li> <li>• Providing information to stakeholders on the facility’s technical assistance needs, identifying local resources available to meet these needs, and, when necessary, planning the technical assistance</li> </ul> |

|   |   |  |
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|   |   | <p>necessary to further strengthen the facility’s capacities and enhance of the quality of the services it provides for PLHIV.</p> <p>The CLASS technique covers several areas.</p> <p><i>Administration:</i> organizational structure; administration and management; strategic and short-term planning; management of available resources; monitoring of programs; HR management, policy, and procedures; licenses, certifications, and permits; crisis management; liability protection; quality assurance; supply management system; cooperation; and communication and information systems.</p> <p><i>Finance:</i> expenditures and revenues; labor reimbursement and rewards; accounts and payments; accounting systems; accounts payable and cash flow; fixed assets; inventory and procurement procedures; and management of expenditures.</p> <p><i>HIV Counseling and Testing:</i> HIV processes and procedures; staff and range of services; laboratory diagnostics; referral system and cooperation with other organizations; public mobilization; awareness-raising and preventive activities with the public and at-risk groups; promotion of HIV testing; and assurance of quality of counseling and testing services.</p> <p><i>Clinical Services:</i> range, quality, completeness, sustainability, and continuity of health care services for HIV prevention, diagnosis, and treatment; technical provision of clinical services; efficiency of clinical mentoring support; quality improvement; support for clinical services decentralization and technical assistance needs assessment.</p> |
| 6 | Participation of facility staff in the assessment | <p>An assessment can involve the following specialists:</p> <p><i>Administration</i></p> <ul style="list-style-type: none"> <li>• Facility or deputy director</li> <li>• The head of the organization and methodology unit</li> <li>• HR</li> <li>• The head of the monitoring and evaluation (M&amp;E) unit</li> <li>• Program manager (when necessary)</li> </ul> <p><i>Finance</i></p> <ul style="list-style-type: none"> <li>• The head of the economy or finance unit, or his/her deputy</li> <li>• An economist</li> <li>• An accountant</li> </ul> <p><i>HIV Counseling and Testing</i></p> <ul style="list-style-type: none"> <li>• The HCT coordinator</li> <li>• An infectionist</li> <li>• A psychologist</li> <li>• A nurse</li> <li>• The head of the lab unit</li> <li>• A counselor</li> <li>• A social worker working with HCT clients</li> </ul> <p><i>Clinical Services</i></p> <ul style="list-style-type: none"> <li>• The deputy chief physician</li> <li>• The head of the outpatient or inpatient unit</li> <li>• An infectionist</li> <li>• A pharmacist and/or the person in charge of medication storage</li> <li>• A nurse</li> <li>• A social worker working with patients.</li> </ul>   |

|   |   |  |
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|   |   | <p>Expected level of participation: the key staff should participate in the opening session and the quality assessment, and be present and ready to answer questions posed by assessment team members.</p> <p>Staff interviews can be conducted both individually and in groups. Management should not be present during staff interviews.</p> <p>The key specialists in each area will participate in the action planning session.</p> <p><b>Note:</b> <i>In working with facility staff, the assessment team should not disrupt the continuity, completeness, or quality of client/patient services.</i></p>   |
| 7 | Tentative list of documents to be reviewed by the team of experts | <p>Statutory, administrative, and financial documents:</p> <ul style="list-style-type: none"> <li>• Statutory documents establishing the facility.</li> <li>• Internal and external organogram.</li> <li>• Current job descriptions.</li> <li>• The approved regional HIV/AIDS program.</li> <li>• The approved schedule for professional qualification improvement.</li> <li>• The approved facility payroll.</li> <li>• Schedules for monitoring or mentorship visits to lower-level facilities.</li> <li>• Guidelines and regulations governing financial policy and relevant procedures.</li> <li>• The current budget.</li> <li>• Expense reports, the asset registry, and the charter of accounts.</li> <li>• Pay schedules and wage-accrual procedures.</li> <li>• Procurement procedures, and the documentation used to establish the bidding committee.</li> <li>• Business travel procedures (accruals and payments).</li> <li>• Orders governing the receipt and distribution of medications, test kits, and medical products.</li> </ul> <p>Documents governing clinical services, counseling, and testing:</p> <ul style="list-style-type: none"> <li>• Infection control directives, and the minutes of infection control commission meetings.</li> <li>• Documents used to establish the medical care quality control commission and its procedures; the minutes of medical care quality control commission meetings; and reports on medical care quality improvement activities.</li> <li>• Cooperative agreements NGOs.</li> <li>• Current lab test standards.</li> <li>• Records and reports related to receipt, storage, and flow of medications.</li> <li>• Documents governing appointment of persons responsible for: <ul style="list-style-type: none"> <li>– Receipt, storage, and flow of medications.</li> <li>– ART.</li> <li>– PMTCT.</li> <li>– HCT.</li> </ul> </li> <li>• Documentation regarding disposal of medications and medical products.</li> <li>• Reports on the results of technical and advisory support visits.</li> <li>• Outpatient primary records (form 025/o): <ul style="list-style-type: none"> <li>– Adults 18 years of age and older, and children up to 18 years of age, including pregnant women.</li> </ul> </li> </ul> |

|   |   |  |
|---|---|--|
|   |   | <ul style="list-style-type: none"> <li>– Before prescription of ART.</li> <li>– Patients prescribed ART.</li> <li>– Patients who have died.</li> <li>– Patients who have dropped out of ART.</li> <li>• HIV post-exposure prophylaxis protocols.</li> <li>• Reports on HCT supervision.</li> <li>• Forms used to refer counseling patients from HCF or NGOs to the Oblast AIDS Center.</li> <li>• HIV antibody lab test logs.</li> <li>• External and internal quality control reports for laboratory tests.</li> <li>• Rapid-testing registration logs.</li> </ul>  |
| 8 | Preparation of the facility for assessment                          | <p>Preparation of the facility for assessment requires:</p> <ul style="list-style-type: none"> <li>• Informing all facility staff about the objectives and timelines of the assessment, and its expected results.</li> <li>• A brief presentation (10 minutes) by the facility, to cover its activity as a whole, and the range of clinical—and in particular HCT—services provided; a brief overview of epidemiological conditions and the composition of the outpatient monitoring group; staffing; and levels of decentralization and cooperation with other facilities.</li> <li>• Presenting key reference documents to the review team before the assessment commences.</li> <li>• Preparing an action planning session, determining its time and location, and inviting partner organizations to participate.</li> </ul> <p>Resolution of organizational issues (when required).</p>  |
| 9 | Brief overview of the CLASS assessment process; assessment findings | <p>The CLASS facility assessment process comprises the following steps:</p> <p><i>Opening session:</i> held by oblast or raion leadership, in conjunction with management at the facility to be assessed, to present information about the CLASS assessment. This session enables administration and staff to become familiar with the objectives of the visit and the members of the team of experts. At the same time, it enables the experts to obtain information about the history and structure of the facility, review the services being provided, determine epidemiological conditions, and outline the problems faced most often by the facility.</p> <p><i>Facility tour:</i> The team familiarizes itself with the facility by following the client/patient pathway to get an idea of the range of services available on site.</p> <p><i>Information collection:</i> The team interviews facility staff and study documents to clarify or confirm the information they have collected (see Annex 9 for).</p> <p><i>Debriefing sessions:</i> Once the facility tour has been completed, interviews have been conducted, and the required documentation has been reviewed, the experts conduct debriefing sessions:</p> <ol style="list-style-type: none"> <li>1) with facility management to inform the director of the preliminary assessment findings, and obtain consent to making the findings public.</li> <li>2) with facility staff to present the assessment findings, and outline strengths, weaknesses, and areas for improvement. At this time, recommendations are provided, and next steps outlined.</li> </ol> <p>An action planning session is conducted separately, on a day following completion of the assessment. This session takes place with a representative of the facility, the team of experts, and the partner organizations working in the field of HIV/AIDS who were invited to participate.</p> |

|  |  |   |
|--|--|---|
|  |  | <p>The action plan requires:</p> <ul style="list-style-type: none"> <li>• Planning steps and actions that will enable capacity strengthening and improvement of activities at the facility.</li> <li>• Seeking out and discussing all accessible local resources that can be channeled to strengthen the capacity of the facility.</li> <li>• Identifying those persons or organizations that will be responsible for taking steps to improve the activity at the facility.</li> <li>• Planning and agreeing on timelines required to implement suggested actions.</li> <li>• Identifying additional technical assistance required.</li> </ul> <p>The action planning session should result in a detailed plan of action, agreed upon by all parties, to further capacity strengthening and quality improvement in the facility's services. The action plan document is held by the facility director, with copies sent to the expert team lead, persons responsible for implementation of the suggested actions, and other stakeholders.</p> <p>Within four to six weeks following completion of the assessment, the team drafts a facility visit report to be sent to the facility director, the UCSDDC, the health care department, and other stakeholders.</p> <p>The facility assessment findings are qualitative, and can be used by facility management primarily to meet the facility's own needs, and in particular to identify priority areas for further improvement and capacity strengthening, as well as to seek out necessary technical assistance resources at the regional and national levels.</p> <p>However, best practices of the facility can be extended to services quality improvement at other facilities. At the national level, the findings can be used for efficient allocation of resources, program planning, identification of technical assistance needs, and location of additional resources.</p> <p>The action plan can also be used to monitor further development and progress in treatment, care, and support programs for PLHIV.</p> |
|--|--|---|

## Annex 11. Sample of the CIASS Facility Assessment Agenda

The approximate duration of the CIASS assessment in one facility is 2–3 days. However, this can be changed to accommodate the range of services being provided and the geographical location of facility departments or branches. The time allocated for the assessment should be sufficient for a detailed and thorough analysis of the facility’s activities and provided documents.

The time for commencement and completion of the assessment can be changed to accommodate its conditions.

| Time                       | Activity   |
|----------------------------|--|
| <b><i>Day One</i></b>      |  |
| 9:30 a.m. –<br>10:30 a.m.  | Greetings and assessment team introductions<br>Presentation of visit goals<br>Description of the CIASS technique<br>Facility presentation                            |
| 10:30 a.m. –<br>11:00 a.m. | Facility tour (following the patient pathway)  |
| 11:00 a.m. –               | Staff interviews and document review   |
| 1:00 p.m.                  | Lunch  |
| 1:00 p.m. –<br>1:30 p.m.   | Continuation of staff interviews and document review   |
| 1:30 p.m. –<br>3:00 p.m.   | Assessment team debriefing<br>Discussion of Day One findings<br>Action planning for Day Two<br>Discussion  |
| <b><i>Day Two</i></b>      |  |
| 9:30 a.m. –<br>11:30 a.m.  | Continuation of staff interviews and document review.  |
| 11:30 a.m. –<br>1:00 p.m.  | Assessment team debriefing<br>Discussion of assessment findings<br>Identification of best practices and areas for improvement<br>Formulation of key recommendations. |
| 1:00 p.m. –<br>1:30 p.m.   | Lunch  |
| 1:30 p.m.<br>–2:30 p.m.    | Final session with the facility director<br>Presentation of assessment findings<br>Identification of issues to be presented to facility staff                        |
| 2:30 p.m. –<br>4:00 p.m.   | Final session with facility staff<br>Presentation of assessment findings<br>Q&A and discussion   |

## **Annex 12. Procedures for the First Visit to the Facility by the CIASS Assessment Team**

*Opening session. Greetings and introductions. (15–20 minutes).*

The opening session consists of two parts.

*The first part of the opening session* is run by the assessment team lead; it should last no longer than 15 minutes, and cover the following:

- Acknowledgment of the director of the facility (or the oblast health care department) and the staff for their time.
- Introduction of all members of the assessment team.
- Outlining the key goals of the team’s visit.
- General overview of the CIASS assessment (processes, procedures, and tools (modules)).
- The schedule and timelines for each stage of the assessment.
- The format and timelines for presentation of findings and conclusions, and possible ways of using them.

*Sample opening session speech:*

The CIASS assessment technique was developed in close cooperation with the International Training and Education Center for Health, University of Washington (I-TECH/UW), with financial assistance from the U.S. Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA), as part of the U.S. President’s Emergency Plan for AIDS (PEPFAR).

This technique is implemented in Ukraine under the leadership of the state institution “Ukrainian Center for Socially Dangerous Disease Control under the MOH of Ukraine.”

Unlike traditional approaches, CIASS is not a control tool; it requires the participation of both experts and representatives of the facility or organization being assessed.

A CIASS assessment is conducted to explore best practices, and identify current problems and needs for the purpose of further strengthening available services, improving service quality, and broadening the range and volume of services provided.

As part of the assessment, special attention is given to the following:

- Efficient use and management of available resources.
- Program management and administration.
- Securing financial sustainability.
- Strengthening human resources and managerial capacities.
- Ensuring comprehensive, quality clinical and social services, including HCT.

The following four modules will be used to perform the assessment:

### 1. Administrative Module

This module is intended to assess the administrative capacity of the facility, and the quality of its program and resource management.

### 2. Financial Module

This module is intended to assess the financial stability of the facility and its programs, as well as its financial management activities.

### 3. HCT Module

This module is intended to assess the quality of HCT processes and procedures.

### 4. Clinical Module

This module is intended to assess the range, quality, sustainability, and uninterrupted provision of HIV prevention, diagnostic, and treatment services.

During the assessment, the members of the assessment team will conduct interviews with facility staff, and review primary records and reports concerning the area of activity being assessed.

The assessment will last two working days. The work will start at 9:30 a.m. on both days, and end at 4:30 p.m., with a 30-minute lunch break at 1:00 p.m.

*The second part of the opening session* is run by the representative of the facility being assessed; it should last 15–20 minutes, and provide a general overview of the facility:

- History of the facility and its activity.
- Range of services being provided.
- Sources of financing.
- Staffing.
- Number and breakdown of clients/patients.
- Pharmacological support for prevention and treatment programs.
- Information systems.
- Facility plans for further development
- The major challenges the facility faces that have an impact on quality and sustainability of services being provided.

*Facility tour (30–60 minutes)*

The assessment team should follow the entire route typically undertaken by the client/patient upon coming to the facility to obtaining a service. During the facility tour, special attention shall be paid to infection control, observation of client/patient confidentiality, and accessibility and usability of services for clients/patients.

The team's findings will be presented immediately following completion of the assessment, in order to ensure participation of all facility staff in the discussions.

Subsequent to presentation of assessment findings, a separate meeting will be conducted with all stakeholders; an action plan will be drafted to incorporate all recommendations on capacity strengthening and improvement of service quality; and steps will be made to implement the recommendations, specifying responsible persons or entities, timelines, and required resources.

A written report subsequent to the findings will be presented within four to six weeks following completion of the assessment.

### Annex 13. Sample Action Plan

Assessment dates \_\_\_\_\_

Facility assessed \_\_\_\_\_

Full name of the facility director \_\_\_\_\_

Team of experts:

Lead \_\_\_\_\_

Administrative Module expert \_\_\_\_\_

Financial Module expert \_\_\_\_\_

HCT Module expert \_\_\_\_\_

Clinical Module expert \_\_\_\_\_

#### Action Plan

| <b>Module</b>  | <b>Activities</b>  | <b>Responsibilities</b>   | <b>Deadlines</b>                                    | <b>Resources/<br/>Technical<br/>Assistance<br/>Required</b>                                   |
|--|--|---|---|---|
| <p>1. <i>Activity area in need of further strengthening</i></p> <p><b>Recommendations:</b><br/><i>recommendations to ensure significant improvements</i></p> | <p><i>Steps to enable implementation of recommendations and ensure capacity strengthening</i></p> <p>1.<br/>2.</p> | <p><i>Name of the institution/facility/organization/position, and full name of the person in charge</i></p> | <p><i>Timelines for implementation of steps</i></p> | <p><i>Necessary additional resources for technical and/or other assistance identified</i></p> |

Date

**Facility director**

**Lead of the team of experts**

*Signature*

*Signature*

**Full name**

**Full name**

**Persons responsible for implementation of suggested activities**

## **Annex 14. Sample of a Written CIASS Report**

### **Facility CIASS Assessment Report**

Assessment dates: *from* \_\_\_\_\_ *to* \_\_\_\_\_ (*day, month, year*)

***Names of the facility (facilities) assessed:***

***Facility No. 1***

***Facility No. 2***

***Facility No. 3***

## **Contents**

Acknowledgements

Acronyms and Abbreviations

### ***Section I. Brief Overview of the CLASS Technique***

- Introduction
- Background/Description of the CLASS Technique
- Objectives for the CLASS Assessment in (*name of the administrative territorial unit*)

### ***Section II. Characteristics of the Facility (Facilities) Assessed***

- History of the facility and its activities
- Epidemiological conditions in the region
- Range of services being provided
- Sources of financing
- Number and breakdown of clients/patients
- Information systems
- Other information

### ***Section III. Findings of the Assessment Conducted in (name of the administrative territorial unit)***

#### ***3.1. Name of the facility assessed. Facility No. 1***

##### ***3.1.1. Overview of Administration***

- Strengths
- Areas for improvement, recommendations

##### ***3.1.2. Overview of Finance***

- Strengths
- Areas for improvement, recommendations

##### ***3.1.3. Overview of HCT***

- Strengths
- Areas for improvement, recommendations

##### ***3.1.4. Overview of Clinical Services***

- Strengths
- Areas for improvement, recommendations

#### ***3.2. Name of the facility assessed. Facility No. 2 and so on***

##### ***3.2.1. Overview of Administration***

- Strengths
- Areas for improvement, recommendations

##### ***3.2.2. Overview of Finance***

- Strengths
- Areas for improvement, recommendations

##### ***3.2.3. Overview of HCT***

- Strengths
- Areas for improvement, recommendations

##### ***3.2.4. Overview of Clinical Services***

- Strengths
- Areas for improvement, recommendations

***Section IV. Recommendations to Be Addressed at the National Level***

- a) Administration
- b) Finance
- c) HCT
- d) Clinical Services

***Annexes***

Annex 1. Action plan for *(name of the administrative territorial unit)*

Annex 2. List of participants and contacts

## **Section I. Brief Overview of the CLASS Technique**

### **1. Introduction**

With the help of specialists from (*name of the institution which provided consultative support for the assessment*); *name of the institution which performed principal coordination of the assessment*), between \_\_\_\_ and \_\_\_\_ (day, month, year), the assessment was conducted at the facility (facilities) operating in the area of PLHIV treatment, care, and support for further strengthening the system of services provided in/at (*name of the administrative and territorial unit*). This assessment was performed using the CLASS technique.

The team of experts included designated specialists who were duly trained and certified to conduct CLASS assessments.

The team of experts is composed of specialists from the following entities:

- *Name of the organization/facility No. 1*
- *Name of the organization/facility No. 2*
- *Name of the organization/facility No. 3*

### **2. Background/Description of the CLASS technique**

CLASS (Clinical Assessment for Systems Strengthening) is a technique for *qualitative* assessment, the ultimate goal of which is to define a participating organization's capacity and identify its capacity-building needs. Unlike traditional approaches to supervision, CLASS is not an audit; it is an assessment process requiring the participation of all parties, including representatives of the facility under assessment. CLASS aims not only to identify a facility's weaknesses or problems, but also to find ways to overcome them. The key objective of a CLASS assessment is to seek out ways and resources to ensure a sustainable, continuous process for providing quality services. The specific objectives of the CLASS assessment are:

- Creating opportunities for a detailed, in-depth assessment of the administrative, financial, and technical capacities of the PLHIV treatment, care, and support programs being implemented by governmental and non-governmental institutions, supported by state or local budgets and funds of international technical assistance projects, with active participation of the facilities under assessment.
- Creation of practical action plans by facility representatives for strengthening the system for providing services for PLHIV, and immediately implementing the steps outlined.
- Sharing with stakeholders information about technical assistance needs, identifying local resources for meeting those needs, and, when necessary, planning technical assistance for the purpose of further strengthening capacity and improving the quality of services for PLHIV.

The CLASS technique is a joint product of I-TECH and HRSA, based on more than ten years of analysis of HIV prevention and treatment programs in the USA. The CLASS tool comprises five modules, which, in fact, are topic-specific guides for conducting in-depth interviews. Following negotiations with Ukrainian counterparts, the following four CLASS modules were adapted for use in Ukraine:

*Administration:* organizational structure; administration and management; strategic and short-term planning; management of available resources; monitoring of programs; HR management, policy, and procedures; licenses, certifications, and permits; crisis management; liability protection; quality assurance; supply management system; cooperation; and communication and information systems.

*Finance:* expenditures and revenues; labor reimbursement and rewards; accounts and payments; accounting systems; accounts payable and cash flow; fixed assets; inventory and procurement procedures; and management of expenditures.

*HIV Counseling and Testing:* HIV processes and procedures; staff and range of services; laboratory diagnostics; referral system and cooperation with other organizations; public

mobilization; awareness-raising and preventive activities with the public and at-risk groups; promotion of HIV testing; and assurance of quality of counseling and testing services.

*Clinical Services:* range, quality, completeness, sustainability, and continuity of health care services for HIV prevention, diagnosis, and treatment; technical provision of clinical services; efficiency of clinical mentoring support; quality improvement; support for clinical services decentralization and technical assistance needs assessment.

### A CLASS review team

#### Members of the team for a CLASS assessment at (name of the facility)

| No. | Full name of the team member | Organization                                       | Assessment Area                                |
|-----|------------------------------|--|--|
| 1.  | Full name                    | Organization where the assessment specialist works | Activity area to be assessed by the specialist |
|     |                              |  |  |

#### 3. Objective of the assessment in (name of the administrative territorial unit):

Following an agreement with the management of (the name of the facility (facilities) assessed (hereinafter – the short name), a CLASS assessment was planned and conducted between \_\_\_\_ and \_\_\_\_ (day, month, year) in (number of facilities) facilities, in particular: (names of the assessed facilities: Facility No. 1 (city 1), Facility No. 2 (city/village 2), Facility No. 3 (city/village 3).

**The overall goal of CIASS.** The goal of the assessment team’s visit was to define best practices, problems, and needs at the facilities under assessment, for the purpose of strengthening and expanding the system of available treatment, care, and support services for PLHIV.

#### The specific objectives of the visit were to assess:

- Effective and efficient use/utilization and management of available resources.
- Effective facility and program management.
- Ways to ensure the success, continuity, and completeness of planned action steps.
- Ways to ensure the financial sustainability of the facility.
- The strength of human resources and managerial capacities.
- Ways to ensure comprehensive, quality clinical and social services, as well as HIV prevention, counseling, and testing services.

The data collection methods used by the CIASS assessment team required in-depth interviews with facility management and staff, observation of facility operations, study of the client/patient pathway, and analysis of documentation.

The following findings are presented for each of the four CIASS assessment modules (Administration, Finance, Clinical Services, and HCT Services):

- **Strengths:** systems that function well.
- **Areas for improvement:** missing or imperfect systems, procedures, and processes of documentation management; insufficient quality of services provided; and areas of non-compliance with standards.
- **Recommendations:** recommendations for resolution at the regional level of issues identified.

*Section III. Findings of the Assessment in (name of the region)*

**General Overview**

Development of the HIV/AIDS epidemic

**3.1. Facility No. 1**

Started operations in \_\_\_\_\_

Located at \_\_\_\_\_

Key units of the facility:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

**3.1.1. Overview of Administration**

- Strengths
- Areas for improvement, recommendations
- \_\_\_\_\_

Recommendations: \_\_\_\_\_

- \_\_\_\_\_

Recommendations: \_\_\_\_\_

**3.1.2. Overview of Finance**

- Strengths
- Areas for improvement, recommendations
- \_\_\_\_\_

Recommendations: \_\_\_\_\_

- \_\_\_\_\_

Recommendations: \_\_\_\_\_

**3.1.3. Overview of HCT**

- Strengths
- Areas for improvement, recommendations
- \_\_\_\_\_

Recommendations: \_\_\_\_\_

- \_\_\_\_\_

Recommendations: \_\_\_\_\_

**3.1.4. Overview of Clinical Services**

- Strengths
- Areas for improvement, recommendations
- \_\_\_\_\_

Recommendations: \_\_\_\_\_

- \_\_\_\_\_

Recommendations: \_\_\_\_\_

**3.2. Facility No. 2**

Started operations in \_\_\_\_\_

Located at \_\_\_\_\_

Key units of the facility:

- 
- 
- 

**3.2.1. Overview of Administration**

- Strengths
- Areas for improvement, recommendations

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

**3.2.2. Overview of Finance**

- Strengths
- Areas for improvement, recommendations

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

**3.2.3. Overview of HCT**

- Strengths
- Areas for improvement, recommendations

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

**3.2.4. Overview of Clinical Services**

- Strengths
- Areas for improvement, recommendations

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

• \_\_\_\_\_

Recommendations: \_\_\_\_\_

**Section IV. Recommendations to Be Addressed at the National Level**

**A. Administration**

Recommendations: \_\_\_\_\_

Recommendations: \_\_\_\_\_

\_\_\_\_\_

B. Finance

Recommendations: \_\_\_\_\_

Recommendations: \_\_\_\_\_

C. HCT

Recommendations: \_\_\_\_\_

Recommendations: \_\_\_\_\_

D. Clinical Services

Recommendations: \_\_\_\_\_

Recommendations: \_\_\_\_\_

Facility where the expert is employed  
(Administration)

\_\_\_\_\_ full name  
signature

Facility where the expert is employed  
(Clinical Services)

\_\_\_\_\_ full name  
signature

Facility where the expert is employed  
(HCT)

\_\_\_\_\_ full name  
signature

Facility where the expert is employed  
(Finance)

\_\_\_\_\_ full name  
signature

## **Information to be Incorporated in the Facility Assessment Report**

1. Description of the CLASS technique:
  - Assessment tools
  - Data collection methods
  - Goals and objectives of the assessment
2. Information about the facility assessed:
  - Address and contact information
  - Director's full name, position, and contact information
  - The facility's brief:
    - Area(s) of activity
    - Units
    - Projects implemented
    - Partner organizations
3. Members of the assessment team:
  - Team lead
  - Reviewers for each area
    - Full names
    - Employers
    - Positions
    - Contact information
4. Assessment of the different areas within the facility:
  - Strengths
  - Processes in need of improvement
  - Problems identified
  - Recommendations to improve activities and resolve problems at the facility
5. Conclusions:
  - General assessment of facility performance
  - Whether or not solutions were found for all problems identified
  - Whether problems identified exist at other facilities of the same type, or are unique to this particular facility

# **Using the Clinical Assessment for Systems Strengthening (CLASS) Technique for Monitoring the HIV/AIDS Response Performance at Ukrainian Health Care Facilities**

**(Guidelines)**

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