WORLD HEALTH ORGANIZATION
EUROPE

How to become a WHO-recognized National Influenza Centre:

Guidance on the process for influenza laboratories in the WHO European Region

Authors

WHO Regional Office for Europe
Dr Caroline Sarah Brown
Dr Dmitriy Pereyaslov

Contributors

WHO headquarters
Dr Wenqing Zhang
Dr Terry Gail Besselaar

WHO Lyon Office
Dr Joanna Zwetyenga

WHO Collaborating Centre for Reference and Research on Influenza
Dr John McCauley, National Institute for Medical Research, United Kingdom

Address requests about publications of the WHO Regional Office for Europe to:
Publications
WHO Regional Office for Europe
Scherfigsvej 8
DK-2100 Copenhagen Ø, Denmark
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Purpose of this document

The purpose of this document is to clarify to Member States, to national influenza laboratories and to institutions recognized by WHO as National Influenza Centres (NICs) the process of obtaining WHO recognition as a National Influenza Centre (NIC)[1]. Recognition by WHO is the formal acknowledgment that the national influenza laboratory complies with the WHO NIC terms of reference (ToR).[2]

Background

The WHO Global Influenza Surveillance Network (GISN) was established in 1952 and currently includes 134 NICs in 104 WHO Member States.[3] WHO Collaborating Centres for reference and research on influenza[4] and WHO reference laboratories for diagnosis of influenza A/H5 infection [5]. All Member States of the WHO European Region with influenza surveillance systems in place have designated national influenza laboratories[6]. These laboratories contribute to influenza surveillance at the national level, they participate in regional surveillance through EuroFlu[7] and the European Influenza Surveillance Network (EISN)[8] and in global surveillance through the GISN. The majority of these laboratories, 50 in 39 countries, are recognized by WHO as NICs.[9] Currently, ten Member States in the region do not have a WHO-recognized NIC.

In the European Region, the WHO Regional Office for Europe is responsible for assessing whether national influenza laboratories should obtain WHO recognition as a NIC, and whether existing NIC should retain their status. Regional Office advises the WHO Global Influenza Programme (GIP)[10] as to whether a laboratory should be recognized or not and together a decision is taken. As the NIC form the cornerstone of the GISN, assessment of their capacities is important to ensure the quality and sustainability of the network and facilitates provision of support by WHO. This document details the process of NIC recognition by WHO.

Process of WHO-recognition of NIC

As described above, the process of formal recognition of an institution* as a NIC in the European Region is performed by Regional Office in coordination with GIP. It consists of three steps which should be followed by countries who wish to obtain WHO recognition of a national influenza laboratory for the first time as well as by those countries with an existing WHO-recognized NIC who have designated a new national influenza laboratory for which they request WHO-recognition. In the latter case, WHO will continue to work with the existing WHO-recognized NIC until the new laboratory has been assessed by WHO to meet the requirements for WHO-recognition following the process described below:

Step 1
A national institution intending to become a WHO-recognized NIC expresses its interest through national authorities to WHO.

- The Ministry of Health (MOH) writes a Letter of intention to Regional Office, either by email to influenza@euro.who.int , or by letter, requesting that the national influenza

* This includes institutions in countries that do not yet have a NIC and reassignment of a NIC to a new institution in the same country

laboratory designated by the MOH becomes recognized as a NIC by WHO. The name and address of the laboratory and proposed head of the NIC should be stated in the letter.

Step 2

An assessment of the capacity of the national influenza laboratory will be conducted by WHO.

- To ascertain whether a laboratory complies with the WHO Terms of Reference for NIC, Regional Office will perform an on-site assessment of the laboratory. To ensure that these laboratories serve as a key technical resource and reference point for national authorities on the laboratory surveillance of influenza, the following aspects are assessed in detail:
    - criteria for the selection of specimens for testing;
    - capacity for testing of specimens and isolating viruses;
    - laboratory staffing and training;
    - available equipment;
    - laboratory procedures, quality and biosafety;
    - reporting of data to WHO;
    - shipment of viruses to WHO CC;
    - availability of government funding.
- In order to assess the above in a standardized manor, and to provide laboratories with a detailed analysis of their strengths and weaknesses, the on-site assessment will be performed using a laboratory assessment tool (LAT) developed by WHO[11,12] and adapted for the assessment of national influenza laboratories (NIC-LAT). (see Annex 1 for a description of the NIC-LAT).
- The on-site assessment is performed by a WHO team, including an expert in laboratory quality and safety and a representative of the WHO CC, London, UK, and according to the following schedule:
    - Day 1 afternoon: laboratory staff are briefed on the assessment;
    - Day 2 morning: WHO team performs the assessment of the laboratory using the NIC-LAT;
    - Day 2 afternoon: WHO team presents the results of the assessment and recommendation as to whether the laboratory should obtain WHO-recognition, as well as any other recommendations considered relevant to improving laboratory procedures and capacities.

Step 3

The outcome of the assessment is discussed with GIP and jointly a decision is made as to whether the institution meets the Terms of Reference for National Influenza Centres.

- Upon agreement with GIP, a letter of recognition to the institution will be prepared for the WHO Regional Director's signature, informing the head of the institution and the government that WHO recognizes it as a National Influenza Centre.
- Should Regional Office recommend that the laboratory not be considered qualified to become a WHO-recognized NIC, and upon agreement with GIP, Regional Office will inform, through the national authorities, the institution formally of the assessment result, will suggest steps for improvements as well as the support that WHO will be able to provide. A new assessment may be planned once improvements have been implemented.

Maintaining NIC status

Recognition as a NIC continues until WHO or the national authorities proposes the termination of the institution's collaboration. Regional Office maintains close contact with NIC in the Region and strives to support NIC in maintaining their status of WHO-recognition. Therefore, Regional Office will provide support to those NIC that request it, as well as to those NIC which do not participate regularly in the following activities:

- Communication and information-sharing with WHO
    - Rapid communication to WHO (through nationally agreed channels of communication and according to obligations under IHR(2005)[13]) of unusual outbreaks of influenza or influenza-like illness, any virus isolate that cannot be readily identified, antigenic drift variants, occurrences of antiviral resistance and other findings that may be of public health concern.
    - Provision of data for the weekly EuroFlu bulletin and to FluNet (NIC in European Union (EU) and European Economic Area (EEA) countries report through the ECDC platform, TESSy)
    - Keeping updated the laboratory profiles on the EuroFlu platform in the "Your personal and country settings" database.
- Sharing of influenza viruses with the WHO Collaborating Centre for Reference and Research on Influenza through the WHO Global shipment project.
- Provide on a regular basis information on laboratory quality, either by submitting to Regional Office the completed NIC-LAT or by providing updated documentation/information on accreditation of the NIC or institute by national and/or international accreditation.
- External Quality Assessments (EQA) organized by WHO
    - NICs that perform PCR are expected to participate in all panels (currently two per year) provided by the WHO External Quality Assessment Project for the Detection of Influenza Viruses by PCR[14]. *Please note we are in the process of developing criteria for successful participation as well as on the provision of certificates.*
    - Participation in EQA organized by Regional Office or partners.
- Ad hoc surveys

Annex 1

Laboratory Assessment Tool (NIC-LAT)

During the past few years, due to the outbreaks of H5N1, the increasing interest of countries to improve surveillance of seasonal influenza and lastly the pandemic, a number of countries in the European Region have established national influenza laboratories and have started to report data to WHO through the EuroFlu platform. Regional Office has worked intensively with these laboratories to help improve their capacities, a key aim being recognition by WHO as a NIC. The process of NIC-recognition through assessment by WHO offers an opportunity to new laboratories joining the European and GISN networks to improve their performance. To make full use of this opportunity, the assessment of laboratories requesting WHO-recognition will occur through an on-site visit using a standardized tool (NIC-LAT) which evaluates the laboratories' influenza-related work as well as the laboratory quality to ensure all countries have influenza laboratories that are operating at similar high standards of performance.

The NIC-LAT combines the existing WHO evaluation NIC checklist with the Laboratory Assessment Tool (LAT), which is based on minimal standards all laboratories should be able to achieve. The LAT has been developed through international collaboration, WHO internal consultation and informal technical working group meetings of experts from different regions of the world as part of WHO strategy to assist countries in improving laboratory quality and IHR core capacities[15] and has been widely used by public health laboratories[16,17,18], including in the European Region. It is considered an efficient tool for putting in place a quality system which will help the laboratory to meet internationally accepted standards such as ISO 15189[†].[19]

The NIC-LAT is a useful tool for self assessment and a detailed user-manual will be available shortly. NIC are encouraged to use it and to share the results with Regional Office. They may also request an on-site assessment to improve their performance and capacity: Regional Office will consider such requests on a case by case basis.

The NIC-LAT will allow WHO to:

- Assess a laboratory in a standardized way
- Automatically generate numerical indicators related to laboratory capacities in different parts called « modules »
- Identify resource and training needs using a standardized approach that can also be used for self-assessment and self-development via a Multilanguage interface
- Follow up the improvement of the same laboratory over time

The NIC-LAT is an MS Excel file which includes 17 worksheets called «modules»:

Laboratory details module

- **Laboratory details:** Laboratory's contact details and general information on its budget and performance on the previous years.

[†] ISO (International Organization for Standardization), ISO 15189:2007 is for use by medical laboratories in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognising the competence of medical laboratories.

Assessment results modules

- **Summary:** A full summary of evaluation and assessment of the laboratory with NIC-LAT.
- **All indicators:** A visual summary of the evaluation of each indicator (see Figure 1 below).
- **Export:** this worksheet represents all the indicators resulting of the assessment for export to an eventual database, allowing comparison of results from multiple assessments.
- **Export checklist:** this worksheet will summarize all information collected on the laboratories practice concerning influenza and will be sent to GIP.

Language Module

- **Language:** this worksheet allows the translation of the whole tool in the represented languages [‡] in this worksheet and a switch between English and Russian languages.

Specific Modules

- **1-Building facilities and utility service:** includes questions concerning the details of the laboratory facility being assessed and the respondent. This section evaluates laboratory building conditions, water and electricity supply of the laboratory.
- **2-Organisation and Human resources management:** This module concerns staff, their training and working conditions at the laboratory. (E.g. the number of days and hours of opening, procedures in emergency cases handled outside the opening hours).
- **3-Laboratory's instruments and equipment:** includes questions targeting the equipment status of the laboratory, its identification and maintenance. Recommended equipments (both quantity and types) are listed in the « Equipment inventory » module. The % of availability of equipment required for a proper function of the laboratory will be evaluated with the help of the **Equipment inventory** module.
    a. **Equipment inventory:** This module is a summary of the minimum equipment (both number and type) recommended in a laboratory that functions as a national influenza laboratory. Its result is included in the evaluation of the module 3-Laboratory's instruments and equipment. It can also be used to evaluate the cost for laboratory equipment needs.
- **4-Biosafety, Hygiene, Security:** includes questions about biosafety practices and documentation, waste management and security of the lab being assessed
- **5-Procurement, reagents and external services:** gathers information concerning procurement, reagents and supplies utilized in the laboratory, their management, and preparation. This module also includes questions concerning financial resources for purchasing reagents and supplies.
- **6-Process management and Quality Control:** This module is dedicated to the examination of the overall quality procedures of the laboratory: quality assurance, the laboratory's sampling procedures, request forms, specimen management, internal and external quality control, analysis procedures and post-analysis processes.
- **7-Documentation:** includes questions about document control and documents available in the laboratory such as procedures, equipment logbooks, records on quality and control of non-conformities.
- **8-Integration in surveillance and public health threats participation:** the laboratory's activities in disease outbreak investigations and involvement in the surveillance system are assessed in this module, which includes reporting of priority diseases to the public health authorities, knowledge of IHR, monthly reports and practices.

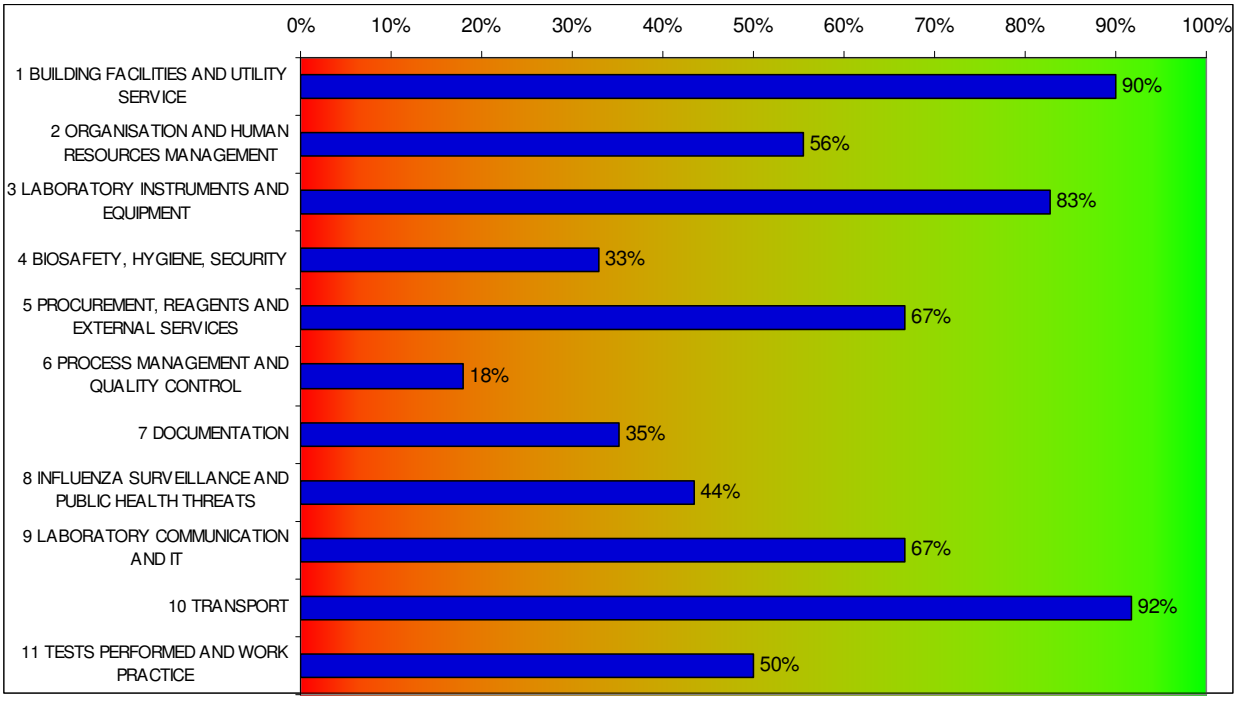
[‡] Currently available in English and Russian

- **9-Laboratory communication and IT:** includes questions about communication capacities, computers' availability and major functions concerning the laboratory information management, data backup and computerized control measures.
- **10-Transport:** This module is dedicated to transport, including questions on training on sample referral and quality of the samples received.
- **11-Test and work practice:** gathers information on the specimens sampled, the tests and analysis actually being performed in the laboratory related to influenza and data reporting.

The assessment proceeds as follows: the assessors explain the main purpose of the assessment to the respondent (the head of the laboratory) and perform the assessment together with the respondent. All data are entered in the NIC-LAT during opening hours, in order to observe staff at work. Calculations of modules indicators are automatically performed when answering to each question. Results are presented graphically in tabulated mode with background color ranging from red to green (Figure 1). This allows easy assessment of each indicator:

- Red: Below 50%, requires significant improvement
- Yellow: Between 50 and 85%, some improvement is necessary
- Green: Above 85%, the laboratory is in good standing

Figure 1. Sheet containing all indicators and their graphic representation.



On the **Summary** page, the general indicator for the assessment of the laboratory is calculated based on an average of the scores obtained for all modules. This shows which modules contribute most to the final general indicator and to interpret which modules need to be improved in order to reach the recommended overall level of 85% (Figure 2).

In general, Regional Office will recommend that laboratories that obtain a score of at least 85% on the general indicator of the NIC-LAT should receive WHO recognition

Figure 2. General indicator calculation

1 BUILDING FACILITIES AND UTILITY SERVICE	90%
2 ORGANISATION AND HUMAN RESOURCES MANAGEMENT	56%
3 LABORATORY INSTRUMENTS AND EQUIPMENT	83%
4 BIOSAFETY, HYGIENE, SECURITY	33%
5 PROCUREMENT, REAGENTS AND EXTERNAL SERVICES	67%
6 PROCESS MANAGEMENT AND QUALITY CONTROL	18%
7 DOCUMENTATION	35%
8 INFLUENZA SURVEILLANCE AND PUBLIC HEALTH THREATS	44%
9 LABORATORY COMMUNICATION AND IT	67%
10 TRANSPORT	92%
11 TESTS PERFORMED AND WORK PRACTICE	50%

GENERAL INDICATOR	**58%**

The NIC-LAT has been successfully piloted in 2010 in the Virology Laboratory, Pathology Department, Mater Dei Hospital Msida, Malta, and the tool has been finalized.

For questions or comments related to this document, please contact
influenza@euro.who.int

References

[1] How to Become a National Influenza Centre and Member of the WHO Global Influenza Surveillance Network [web site]. Geneva, World Health Organization, (http://www.who.int/csr/disease/influenza/NIC_info_21_09_05.pdf, accessed 25 March 2010).
[2] Terms of Reference for National Influenza Centres [web site]. Geneva, World Health Organization, (http://www.who.int/csr/disease/influenza/TORNICs.pdf, accessed 25 March 2010).
[3] WHO Global Influenza Surveillance Network [web site]. Geneva, World Health Organization, (http://www.who.int/csr/disease/influenza/surveillance/en/index.html, accessed 25 March 2010).
[4] WHO Collaborating Centres for influenza and Essential Regulatory Laboratories [web site]. Geneva, World Health Organization, (http://www.who.int/csr/disease/influenza/collabcentres/en/, accessed 25 March 2010).
[5] WHO reference laboratories for diagnosis of influenza A/H5 infection [web site]. Geneva, World Health Organization, (http://www.who.int/csr/disease/avian_influenza/guidelines/referencelabs/en/, accessed 25 March 2010).
[6] WHO European Influenza Surveillance Portal (EuroFlu), EuroFlu Members [web site]. WHO Regional Office for Europe, (http://www.euroflu.org/cgi-files/wiw_members_display.cgi, accessed 25 March 2010).
[7] WHO European Influenza Surveillance Portal (EuroFlu) [web site]. WHO Regional Office for Europe, (http://www.euroflu.org/index.php, accessed 25 March 2010).
[8] European Influenza Surveillance Network (EISN) [web site]. European Centre for Disease Prevention and Control (ECDC),(http://www.ecdc.europa.eu/en/activities/surveillance/EISN/Pages/home.aspx, accessed 25 March 2010).
[9] National Influenza Centres [web site]. Geneva, World Health Organization, (http://www.who.int/csr/disease/influenza/centres/en/index.html, accessed 25 March 2010).
[10] WHO Global Influenza Programme [web site]. Geneva, World Health Organization, (http://www.who.int/csr/disease/influenza/mission/en/, accessed 25 March 2010).
[11] Laboratory Quality Management System (LQMS) training toolkit [web site]. Geneva, World Health Organization, (http://www.who.int/entity/ihr/training/laboratory_quality/lab_qsm_assessment_tool.xls, http://www.who.int/entity/ihr/training/laboratory_quality/lab_qsm_assessment_tool_user_manual.doc, accessed 25 March 2010).
[12] Joint WHO-CDC conference on laboratory quality systems, Lyon, April 2008 -- joint statement and recommendations. Weekly Epidemiological Record [serial on the Internet]. (2008, Aug 8), 83(32): 285-287. ,(http://www.who.int/wer/2008/wer8332.pdf, accessed 25 March 2010).
[13] International health regulations (2005). 2nd ed. Geneva : World Health Organization, 2008. (Electronic access: http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf; http://whqlibdoc.who.int/publications/2008/9789244580417_rus.pdf).
[14] WHO External Quality Assessment Project for the Detection of Subtype Influenza A Viruses by PCR [web site]. Geneva, World Health Organization, (http://www.who.int/entity/csr/disease/influenza/eqa20070706.pdf, accessed 25 March 2010).
[15] International health regulations (2005). 2nd ed. Geneva : World Health Organization, 2008. (Electronic access: http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf; http://whqlibdoc.who.int/publications/2008/9789244580417_rus.pdf).
[16] Assessment tool for core capacity requirements at designated airports, ports and ground crossings [web site]. Geneva, World Health Organization, (http://www.who.int/ihr/ports_airports/PoE/en/, accessed 25 March 2010).
[17] Laboratory Assessment [web site]. Atlanta, International Laboratory-related Resource and Activity Directory, Centers for Disease Control and Prevention (CDC), (http://wwwn.cdc.gov/dls/ila/documents/WHOLaboratoryAssessment.pdf, accessed 25 March 2010).
[18] Tuberculosis Laboratory Assessment Tool [web site]. Atlanta, International Laboratory-related Resource and Activity Directory, Centers for Disease Control and Prevention (CDC), (http://wwwn.cdc.gov/dls/ila/documents/Lab%20assess%20tool3(WHO).pdf, accessed 25 March 2010).
[19] International Organization for Standardization, ISO 15189:2007: Medical laboratories -- Particular requirements for quality and competence. (Electronic access: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=42641).