World Health Organization
REGIONAL OFFICE FOR Europe

GUIDANCE FOR RAPID RESPONSE MOBILE LABORATORY (RRML) CLASSIFICATION

ABSTRACT

Rapid response mobile laboratories (RRMLs) play a crucial role in rapidly responding to and monitoring emergency events and outbreaks within and beyond the WHO European Region. This publication presents a classification system for RRMLs when used in biological events, and the potential deployment and use of RRMLs to cover outbreak detection and response, natural or man-made disasters, and preparedness for mass-gathering events. This classification covers five levels of RRML capacities: Type I (highly compact), Type II (box-based), Type III (medium-scale), Type IV (large-scale) and Type V (full-scale). The classification has three layers that establish the basic requirements and features common to all RRML types, define RRML capacity and throughput, and ensure the flexibility, interoperability and scalability of the response. Implementation of this classification will enable RRMLs to function optimally in the field, increase their interoperability with other rapid response capacities and be used as the foundation for standards development across all five types of RRMLs.

ISBN: 9789289054928

© World Health Organization 2021

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition: Guidance for rapid response mobile laboratory (RRML) classification. Copenhagen: WHO Regional Office for Europe; 2021".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization. (http://www.wipo.int/amc/en/mediation/rules/)

Suggested citation. Guidance for rapid response mobile laboratory (RRML) classification. Copenhagen: WHO Regional Office for Europe; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Cover photos, clockwise from top center: © WHO/Darek Zalewski; © WHO; © WHO/Darek Zalewski; © WHO/Jan Baumann; © WHO/Darek Zalewski; © Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor); © WHO/Darek Zalewski; © WHO/Darek Zalewski

Design and layout: Viktoriya Arkhipenko

World Health Organization
REGIONAL OFFICE FOR Europe

GUIDANCE FOR RAPID RESPONSE MOBILE LABORATORY (RRML) CLASSIFICATION

CONTENTS

Acknowledgements ..... **iv**

Abbreviations ..... **v**

Introduction **1**

Scope **3**

Objectives **3**

Approach for the classification of RRMLs **4**

Layer 1. Common requirements and features **6**

QMS and minimum quality standards 6

LIMS and data exchange 7

Layer 2. Discriminatory variables for RRML **8**

Capability and throughput 8

Biosafety and biosecurity 10

Mobility and logistic requirements 13

Layer 3. Capacity **15**

Modular approach to functionality 15

Database of the capacities of RRMLs **20**

Ethical considerations **21**

Next steps **22**

Standards 22

Coordination in emergencies 22

Workforce development 23

References **24**

Annex I. Overview of the RRML classification **26**

Annex II. Registration form for RRML capacities and needs **28**

Annex III. Registration form for RRML diagnostic modules **32**

Annex IV. Decision tree for configuring RRMLs **33**

ACKNOWLEDGEMENTS

Work on the rapid response mobile laboratory (RRML) classification system was initiated and developed through collaboration between the Robert Koch Institute, the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) and the WHO Regional Office for Europe. This process was initiated under the umbrella of Global Outbreak Alert and Response Network (GOARN) activities in an effort to harmonize and further develop RRMLs in keeping with all rapid response capacities, one of the five priority areas of GOARN work.

The members of the initial RRML classification working group are Dr Jan Baumann, Robert Koch Institute, Germany; Dr Vasilii Kouklev and Dr Anton Lopatin, Rospotrebnadzor, Russian Federation; and Dr Lisa Carter, WHO Regional Office for Europe, Denmark.

Through a series of in-person consultations and discussions designed to consider the capacities and requirements of the entire WHO European Region, this publication was developed from July to September 2019. Following an initial review process with technical advisers within WHO and GOARN partner institutions, the content was reviewed with participants at the First Stakeholder Meeting on Classification and Minimal Standards of the GOARN Mobile Laboratory Rapid Response Capacity in Munich, Germany, in October 2019, and feedback was incorporated to inform the final version of this guidance document. WHO would like to acknowledge the contribution and the joint efforts of all meeting participants in the continued development and work of the RRML classification and standardization process.

ABBREVIATIONS

CBRN	chemical, biological, radiological and nuclear
CRN	chemical, radiological and nuclear
ELISA	enzyme-linked immunosorbent assay
GOARN	Global Outbreak Alert and Response Network
HTS	high-throughput sequencing
HRAF	high-risk of aerosol formation
ISO	International Organization for Standardization
LIMS	laboratory information management systems
ML	mobile laboratory
PCR	polymerase chain reaction
QMS	quality management systems
qPCR	quantitative polymerase chain reaction
RRML	rapid response mobile laboratory

INTRODUCTION

At the Sixty-ninth World Health Assembly in 2016, the WHO Secretariat recommended that WHO should strengthen all public health rapid response capacities to emergencies, including its partnership with the Global Outbreak Alert and Response Network (GOARN), which provides technical support to WHO Member States experiencing a health emergency. Mobile laboratories (MLs) are a crucial component of responses to public health events and have played an important role in response activities, such as the 2014–2016 West African Ebola outbreak. During and following the outbreak, there was a surge in development of both national and international MLs, ultimately without central or standardized coordination. This resulted in inconsistencies in ML capacity, as the structure and capabilities of each ML were determined based on the individual needs and priorities of countries and institutions. Today, MLs can accomplish a wide range of tasks and serve a multitude of purposes (some of which are beyond the remit of this publication).

To address these inconsistencies, it is important to use more precise terminology and to propose a classification system, set of minimum standards and specific coordination mechanisms applicable for both European and global MLs. Applying a standardized approach to this wide spectrum of capabilities offered by partners, and for consideration by the response coordination body, will enable more defined and targeted responses to emergencies to be provided, ensuring that MLs are tailor-made for their purpose. Additionally, the development of this classification structure and further work on defining standards for MLs will enhance and strengthen mutual understanding, communication and coordination among partners and coordinating bodies, and increase the interoperability of MLs and other rapid response capacities, such as emergency medical teams.

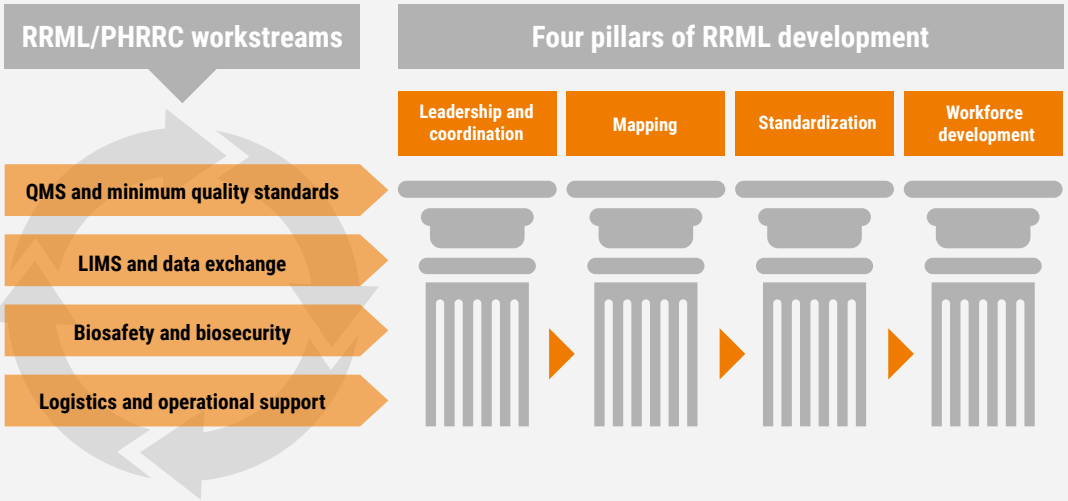
In order to clarify the type of ML addressed in this publication, the term "rapid response mobile laboratory" (RRML) is used to differentiate between MLs used specifically for routine support of national public health systems, and deployable RRMLs that can be used predominantly, but not exclusively, in times of emergency and still support the public health capacities of countries.

This process has been initiated under the umbrella of GOARN activities in an effort to harmonize and develop MLs in keeping with all rapid response capacities, one of the five priority areas of GOARN work.[1] This publication focuses on the classification of RRMLs as a prerequisite for future standardization. The classification is in accordance with the RRML public health rapid response capacity workstreams in the RRML Framework (Fig. 1). The workstreams were initiated during a workshop with GOARN rapid response team partners in Berlin, Germany (March 2017), which recognized MLs as a key response component, and further developed and adopted during a meet-

1 The five priority areas are operational research and tools development; public health rapid response capacities; alert and risk assessment; training; and governance.

ing on GOARN RRML capacities in the WHO European Region (Saratov, Russian Federation, 19–21 November 2018). The four pillars in the RRML Framework should be considered across all workstreams.

Fig.1 The RRML Framework



LIMS: laboratory information management systems; PHRRC: public health rapid response capacities; QMS: quality management systems.

WHO applies an all-hazard approach *(1)* to emergency preparedness and response activities, where the effects on public health of disease outbreaks, natural or man-made disasters, conflict, mass gatherings, or the accidental or deliberate release of chemical, biological, radiological or nuclear (CBRN) agents must be considered. The CBRN approach cannot be applied to the full extent as equipment and expertise may not be represented in the majority of RRMLs. This classification focuses on RRMLs and addresses those deployed in support of biological hazards. Nevertheless, it also considers, but does not explicitly address, the potential inclusion of components to address chemical, radiological and nuclear (CRN) hazards in a modular capacity for initial investigation of the nature of the hazard.

SCOPE

This publication describes a three-layered system of classification separating RRMLs into five types, based on their capabilities and capacities, with a modular approach to expanding functionality, flexibility and interoperability with other rapid response capacities, as well as inclusion of specific diagnostic testing procedures to ensure a targeted response.

OBJECTIVES

The main purpose of this guidance is to define a classification system for RRMLs. This classification will act as a basis for standardization of RRMLs and harmonization with other rapid response capacities. This will strengthen international GOARN RRML responses, as well as responses that are coordinated through other mechanisms, and the RRML response for broader biological hazards and not just high-consequence pathogens. In addition, this systematic classification will achieve the following objectives.

- Strengthen public health rapid response capacities on the global and regional levels, through the provision of defined and targeted response to emergencies, and facilitate the interoperability of RRMLs and rapid response capacities.
- Improve the regional RRML network and aid in the development of RRMLs in other regions.
- Address discrepancies in the RRML definition through the development of a framework and recommendations with GOARN partners, in consultation with countries, to provide the WHO European Region with a more focused vision and strategy for RRMLs.

APPROACH FOR THE CLASSIFICATION OF RRMLs

RRMLs should be classified according to the main workstreams related to RRML standardization. The first two workstreams, *QMS and minimum quality standards* and *LIMS and data exchange*, state generic features that are applicable across all diagnostic laboratories while *biosafety and biosecurity* and *logistics and operational support* are crucial for quantification and classification. In addition, the RRML classification working group identified capability and capacity as important factors in the differentiation of RRML units.

As such, this classification system was developed in three layers (Box 1).

© Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor)

Box 1. Three-layer RRML classification system

LAYER 1

The first layer or foundation establishes the common requirements and features that are consistent across all types of RRMLs, including QMS and LIMS.

QMS and minimum quality standards

LIMS and data exchange

LAYER 2

The second layer comprises discriminatory variables across types of RRMLs, defined by capability and throughput. This layer is composed of biosafety and biosecurity considerations, the degree of mobility needed, and the logistic and operational support requirements.

Capability

Capability is defined as the ability to perform the following functions: manage laboratory activities; perform sample management; conduct testing and analysis for routine and surge capacity; support public health investigations; and report results *(2)*.

Throughput

Throughput is a measure of institutional volume or capacity and a determinant of productivity. In the laboratory, throughput refers to the analysis, processing or testing of multiple samples. Techniques that foster the rapid or simultaneous processing of multiple samples are called high throughput.

Biosafety and biosecurity

WHO guidelines describe biosafety and biosecurity as the ability to handle and/or inactivate pathogens of different risk groups *(3)*.

Mobility and logistic requirements

Mobility comprises the time frame in which RRMLs can be deployed in a given context and the potential for relocation within a given deployment environment. Logistic requirements define the degree of self-sustainability and the ability to plan for an average time of stay of RRMLs.

LAYER 3

This layer comprises well-defined diagnostic modules that can be added to RRMLs to ensure the flexibility, interoperability and scalability of the response, and to define capacity.

Capacity

Capacity consists of output services completed over a defined time period for each capability *(4)*.

Definitions of the stated criteria in Box 1 follow the criteria recently adopted by the European Centre for Disease Prevention and Control in the European Union Laboratory Capability Monitoring System *(5)*. Consequently, this publication classifies RRMLs according to capability, throughput, biosafety and biosecurity, mobility and logistic requirements, and capacity.

LAYER 1. COMMON REQUIREMENTS AND FEATURES

To align the classification to the four proposed workstreams, QMS and minimal quality standards, as well as LIMS and data exchange, should be discussed in relation to the classification process. These workstreams of the RRML Framework should follow common diagnostic laboratory agreements in keeping with international guidelines. These workstreams are part of the formulation of minimal standards in the field and are clarified here to simplify a future RRML harmonization and standardization process.

QMS and minimum quality standards

It is expected that all RRMLs would meet predefined standards and adhere to the same quality assurance mechanisms that apply to stationary laboratories in home institutions, ensuring compliance with both national and international standards *(3,6–12)*. It is understood that it may be a challenge to achieve International Organization for Standardization (ISO) requirements in field conditions (e.g. for waste management), and those challenges will be addressed in the forthcoming RRML standardization process. During this process, QMS specific to RRML will be proposed – based on ISO – that set safe minimum required standards for quality attainable in the field. These determined standards, agreements and protocols should be adhered to across all types of RRMLs.

RRMLs should continue to be enrolled in a quality management and assurance programme in the home country or at an international institution. RRMLs should also be incorporated into existing proficiency testing systems.

LIMS and data exchange

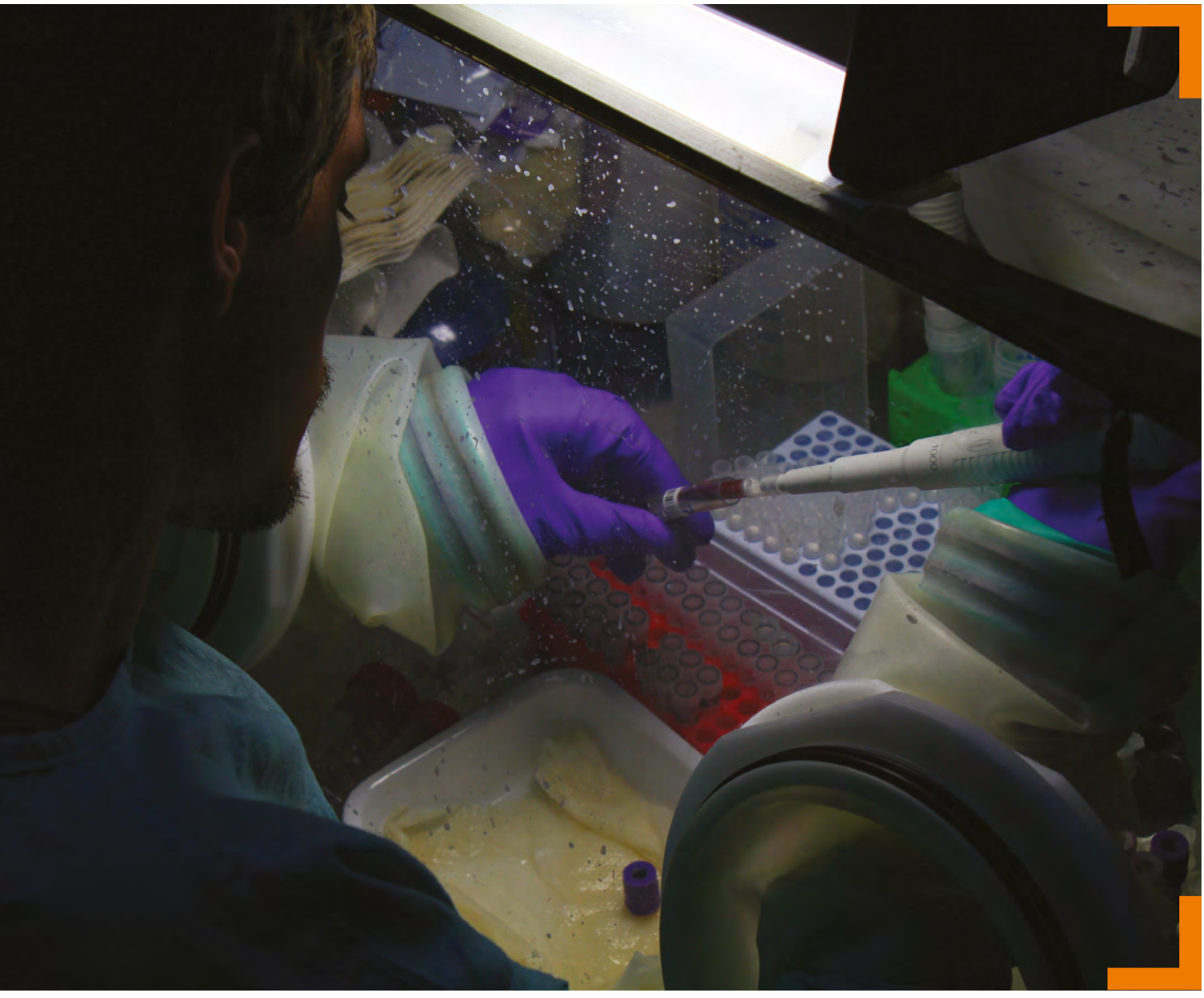
Multiple LIMS have already been established across different RRMLs, with varying fields for data collection. This variety in data indicators, required information, and data sharing and security makes it difficult to standardize the information gathered, as well as the methods by which individual organizations collect and transmit the information. As an alternative, minimal mandatory data fields, to be defined in the RRML standardization process, will be collected and shared with the coordinating body for the response, and will maximize interoperability with health ministries as well as with other rapid response capacity partners, according to agreements and standards. There is a strong need to align RRML data with other data collection tools used/implemented during the response. Standardization of the minimum number of data fields, information collected and the outputs will ensure information can be aggregated and further shared with response partners and stakeholders, as appropriate and in accordance with international data security requirements. Data transfer and exchange will also be coordinated and defined, with appropriate communication pathways and data security procedures, during the forthcoming standardization process.

© WHO/Cristiana Salvi

LAYER 2. DISCRIMINATORY VARIABLES FOR RRMLs

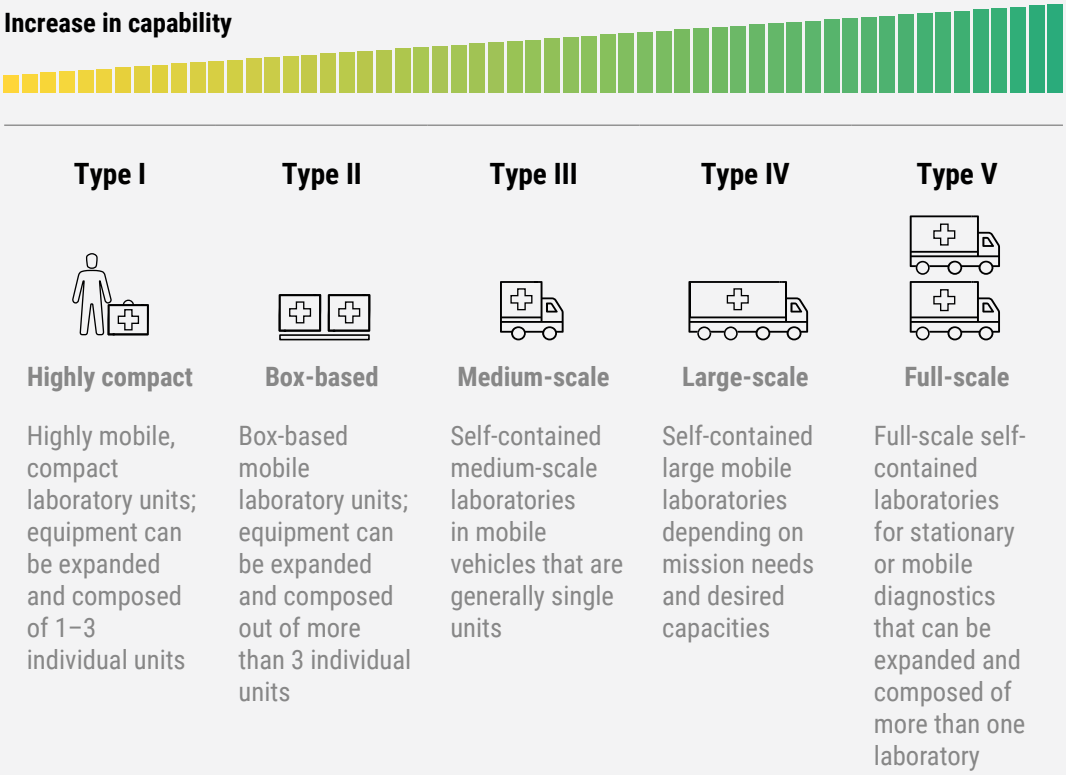
Capability and throughput

The most prominent aspect of RRMLs is their principal capability and their diagnostic daily throughput, which in return influences their deployment time and in-country mobility. As a result, this primary RRML classification is defined according to scale of capability, comprising Type I (highly compact), Type II (box-based), Type III (medium-scale), Type IV (large-scale) and Type V (full-scale) (Fig. 2).



© Jan Baumann

Fig. 2. Layer 2: discriminatory variables for RRMLs



The capability and capacity of an RRML increase from Types I–V. In practice, RRMLs vary greatly in their features so these classifications have been developed to include all configurations, with a view to future proofing the definitions to accommodate for dynamic technologies and circumstances.

Besides the diagnostic capabilities and throughput of RRMLs, additional complementary functions should be considered if available. These may include, but are not be limited to, epidemiological investigation or environmental decontamination, which are not addressed specifically in this publication.

Biosafety and biosecurity

Due to biosafety and biosecurity considerations, not all types of laboratories are recommended to include all modules or to carry out all functions. This is in part because of constraints in capability or throughput, which can restrict important components including decontamination, waste management and more.

The biosafety limitations of each laboratory have been addressed using the pathogen–risk group classification in the WHO Laboratory biosafety manual, third edition *(3)* (Fig. 3).

Fig.3. Classification of pathogens by risk group and RMML type

Source: WHO Laboratory biosafety manual, third edition *(3)*.

Depending on the nature of the situation, the pathogen involved and the testing capacity required, limitations should be put on the procedures that RRMLs can carry out. As indicated in Fig. 3, Risk Groups 3 and 4 can pose a significant threat to the well-being of laboratory workers and entire communities. Type II RRMLs, and in particular Types III–V, have expanded capacities and capabilities that support their operation with the appropriate equipment and staff/human resources to safely work with these higher risk pathogens. The only point where handling of Risk Group 4 would be restricted is for Type I RRMLs. This recommendation is made based on biosafety and biosecurity measures as they relate to pathogen containment and human resources, as Type I RRMLs may not be fully capable of meeting minimal requirements for working with these pathogens, or of having the necessary amount of staff to ensure all protocols are met. If the appropriate support is given to Type I RRMLs on-site, their capability can be potentially increased to include the handling of Risk Group 4.

A risk assessment considering laboratory layout and deployment context should be conducted to identify the risk groups of the pathogens that the RRML is able to properly process while meeting biosafety and biosecurity standards.

Three procedures require special precautions: **sample inactivation, high-risk aerosol-forming (HRAF) procedures** and **pathogen cultivation** *(13)*.

- **Sample inactivation** is a well-established and routine method, but may require special biosafety measures depending on the pathogen and therefore restrict an RRML's ability to conduct the procedure. As an example, Type I laboratories are unlikely to be equipped with biosafety cabinets or isolators and are therefore not necessarily able to fulfil all biosafety requirements for inactivation of high-risk biological agents on a regular basis. Type II RRMLs may be able to inactivate these agents given suitable procedures and required equipment.

- **HRAF procedures** require special precautions with respect to personal protective equipment in order to avoid inadvertent airborne transmission of a pathogen. Both Types I and II RRMLs may need to be equipped with additional measures and equipment to handle highly pathogenic aerosol transmissible and high-risk aerosol-generating pathogens.

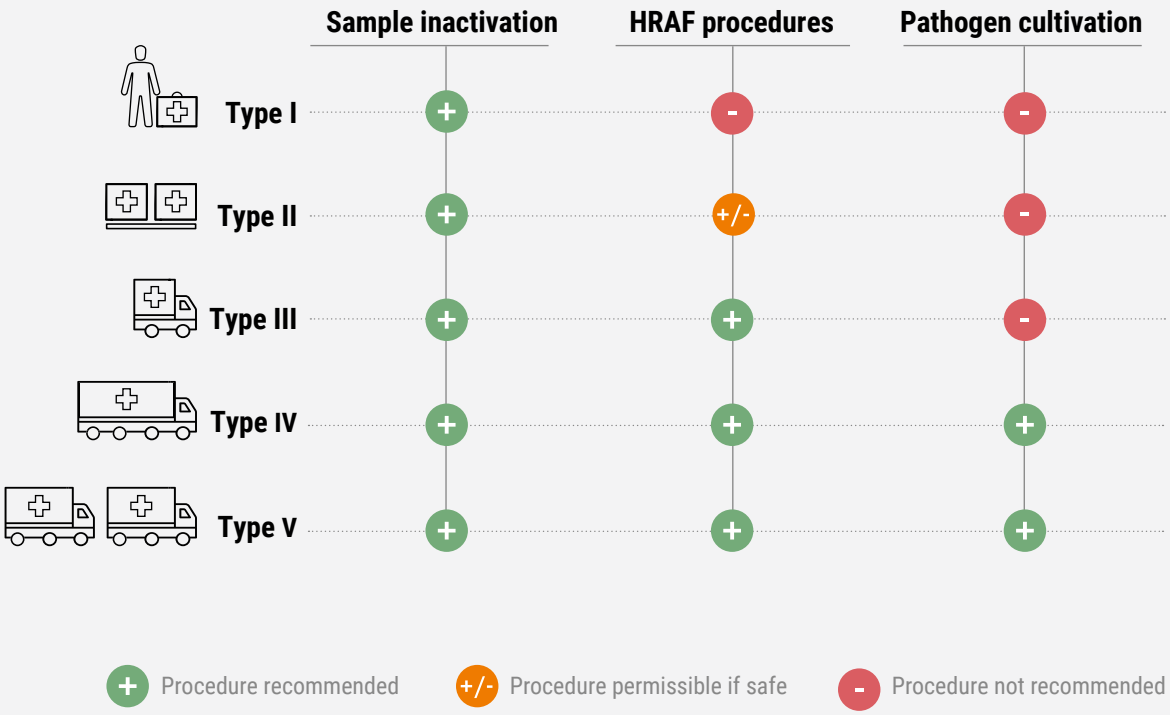
- In contrast to sample inactivation, **pathogen cultivation** may carry more risks for pathogen dissemination and potential infection. The higher concentration and volume of pathogen material may require special measures aimed at sample handling and disposal.

Additional advanced procedures may be crucial for diagnostics, such as bacterial culture; due to containment restriction, these would be challenging or unsafe to conduct in Types I or II RRMLs but may be suitable for higher level RRMLs. For example, without proper biosafety and biosecurity capacities, it would not be appropriate to carry out bacterial or viral culture in a Type I or II laboratory, but this can be achieved in the higher levels RRMLs, while sample inactivation can still be carried out in the lower level RRMLs (Fig. 4). These recommendations are based on the logistic, biosafety and biosecurity capabilities and capacities of the different types of RRMLs. No laboratory,

regardless of type, should undertake pathogenic work of any kind until the proper disposal/inactivation of waste in line with international standards has been assured.

Another consideration taken into account was the possible risk of personnel infection for different laboratory activities. The classification criteria also included the nature of the work done in the RRML, such as sample inactivation or propagation of micro-organisms through viral or bacterial culture, and the ability of the RRML to perform certain procedures having a high risk of aerosol generation. These procedures could include, but not be limited to, centrifugation, homogenization, intensive mixing, ultra-sonication, and handling large volumes or high concentrations of pathogens.

Fig. 4. Summary of procedures recommended by RMML type



High-risk procedures, such as bacterial or viral culture and HRAFs, are recommended only in RRMLs with higher capability and capacity for containment. Special arrangements may be made to allow flexibility in the recommendations, such as the use of HRAFs in Type II laboratories, or arrangements made in other circumstances as an ongoing risk assessment. However, all procedures would be subject to detailed risk assessment; it is not envisaged that pathogen cultivation would be easily achievable for any RRML below Type III.

Mobility and logistic requirements

Different types of laboratories have different degrees of mobility regarding transport and relocation, as well as anticipated levels of self-sufficiency and anticipated length of deployment.

Mobility is determined by the degree of logistic support needed for deployment and the flexibility to relocate RRMLs in the field without the involvement of heavy logistic support. Types I and II RRMLs are rapidly deployable by public planes but may need transportation support for relocation in the field. Types III–V RRMLs have the potential for in-field mobility but rely on additional support during deployment.

Self-sufficiency is the ability for RRMLs to be operational without specific assistance from the host government, including the mode and frequency of RRML resupply. For each type of RRML, this ability would be measured by an expected minimum period of time, to be defined by minimum standards for RRMLs, and is a key requirement for increasing interoperability with other rapid response capacities. As the capacity and capability of RRMLs increase, so too does the level of self-sufficiency required. Self-sufficiency is also an important factor for easing the burden of need and the requirements for deployment on the host country experiencing the emergency. This topic is divided into the categories of **technical** and **logistic sufficiency**.

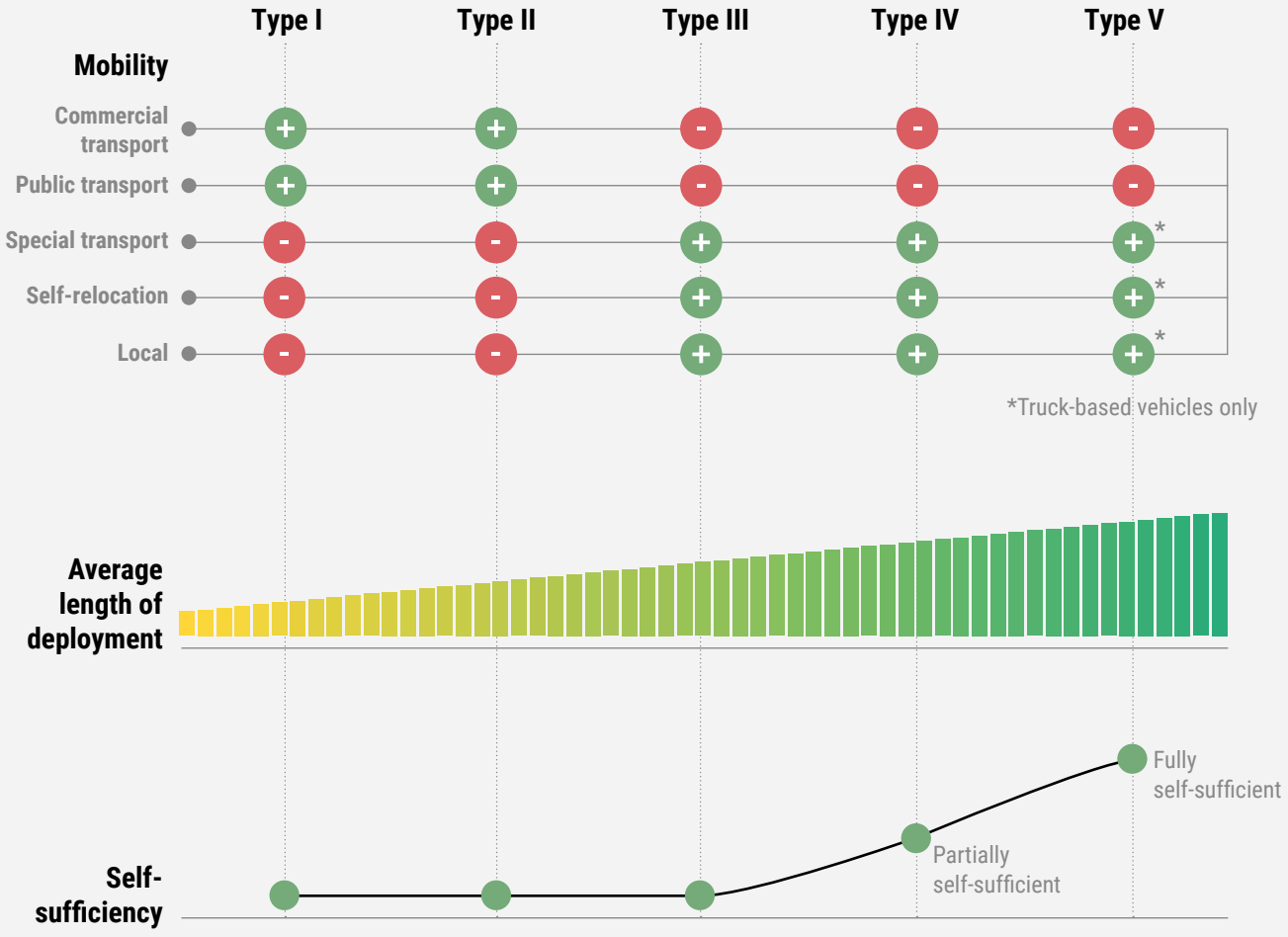
- **Technical self-sufficiency** includes the technical requirements and abilities, such as polymerase chain reaction (PCR), microscopes and other equipment and consumables required to perform essential RRML functions. This should be organized by individual RRMLs, including mode of resupply and communication needs.
- **Logistical self-sufficiency** is much more complicated to attain and comes with a long list of needs, including and certainly not limited to structural requirements (tents, buildings), transport considerations, security, staff accommodation, communication equipment and methods, visa arrangements, day-to-day support for RRML staff, customs procedures, cold chain management and waste disposal capabilities and capacities in the country. In order to cover these needs, national and/or supranational support should be investigated on a case-to-case basis depending on the situation in the field. Therefore, for the purposes of this publication, self-sufficiency standards will be considered in terms of logistic sufficiency.

When considering use of RRMLs, at a minimum, the logistic requirements and degree of self-sufficiency should be considered. The self-sufficiency landscape varies across the five types of RRMLs, and the degree of self-sufficiency required and met depends on the national support available by the deploying country/institution, as well as by the receiving country. Nevertheless, it is paramount for deployment or for the response organization to define the expectation for the level of self-sufficiency for each type of RRML.

Whereas all RRML types should meet technical self-sufficiency requirements, Types I–III are not expected to be self-sufficient logistically due to size and content restriction. In contrast, Type IV should be partially self-sufficient, and Type V RRMLs are expected to be fully self-sufficient due to their increased size and capacity (Fig. 5).

Average length of deployment will remain variable on a minimal deployment timeline: the minimal time frame for which the RRML should be prepared to stay deployed and operate. This will be defined for each RRML type according to the forthcoming standards. For planning purposes, RRMLs need to consider variables associated with average length of deployment, such as human resources and staff rotations, a system of resupply for longer deployments and other needs (such as the technical self-sufficiency considerations previously presented). This will help to harmonize expectations for both the RRML and the receiving country.

Fig. 5. Mobility and logistic requirements by RMML type



LAYER 3. CAPACITY

Modular approach to functionality

Due to the high variability of RRML capacity and capabilities globally, classifying them based on their functions is difficult. Different diagnostic techniques may be required for different scenarios, and as such, different sets of equipment may be viable for the same RRML depending on the situational needs. It is more reasonable to specify RRML functions using a modular approach, with a module comprising the specialized equipment, personal protective equipment and expertise to perform diagnostics as necessary.

A vast range of laboratory techniques can be carried out in RRMLs, which makes it impractical to classify them based solely on their function. A modular approach is used to describe the precise diagnostic functions that RRMLs can perform, with each module defined as an individual laboratory technique or procedure. A module consists of all devices and consumables, as well as experts trained in the technique unless such expertise is already included in the skills of the basic RRML staff. Diagnostic modules are classified as either basic or advanced (Fig. 6).

- Basic modules comprise procedures that have limited needs for laboratory space and consumables. This includes, but is not limited to, quantitative polymerase chain reaction (qPCR), enzyme-linked immunosorbent assays (ELISA) and light microscopy.

- Advanced modules include procedures that are more resource intensive in terms of laboratory architecture, consumables and working time. They may include high-throughput sequencing (HTS),[2] long-term sample storage and pathogen culture.

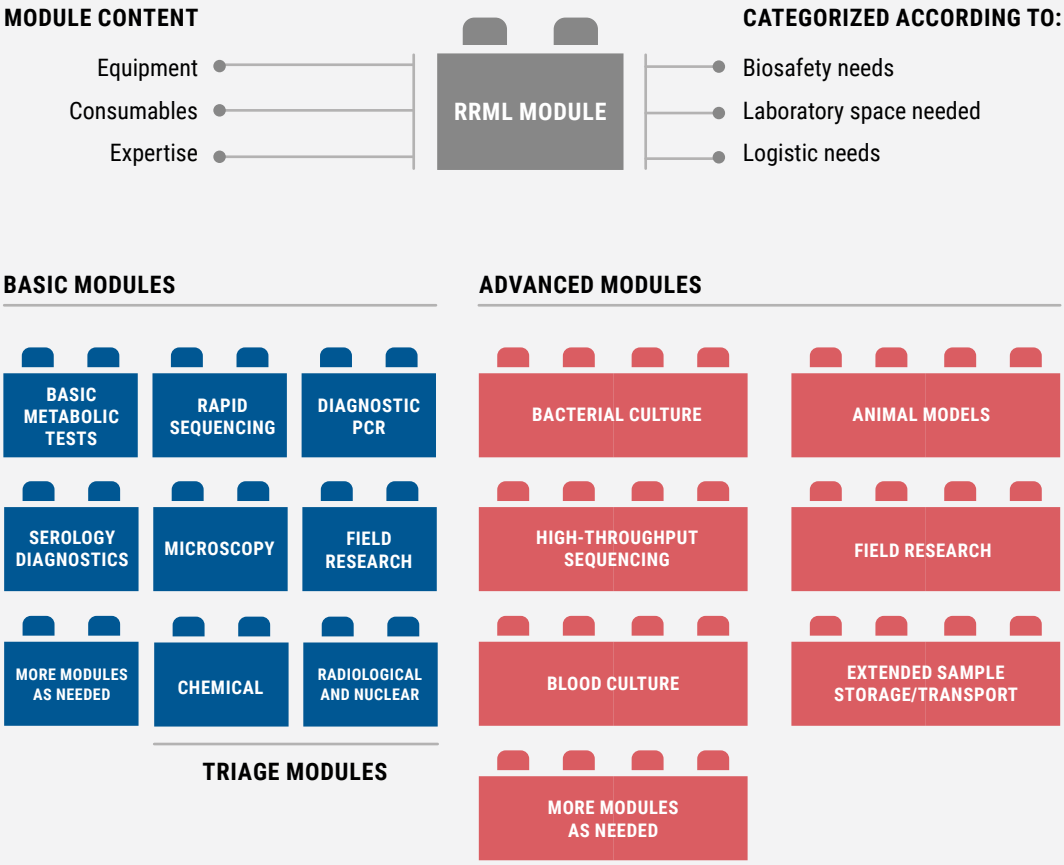
The capability to perform single module tasks depends on the laboratory architecture, biosafety and biosecurity capacities, and human resources. It is thus recommended that RRML Types I–III are limited to include only basic modules, whereas Types IV and V could also include advanced modules. Nevertheless, advanced modules may be included in Types I–III upon clarification that all required biosafety and biosecurity measures are fulfilled, as well as structural and test requirements, and the required expertise is available. Advanced modules are recommended to be deployed only by RRMLs of Types IV and V because they are more resource intensive.

Even though, the main purpose of RRMLs is to support national public health systems during emergencies, field research may be incorporated for further outbreak investigation. Depending on the applied procedures and the scope of the field research, these modules are categorized as either basic or advanced and will be further defined during the standardization process.

2 Note that HTS should be differentiated from rapid long-read sequencing, using nanopore technology, which may be appropriate for a basic module but is not the preferred method of HTS in all situations. HTS technologies include Illumina's and Ion Torrent's platforms.

The modules presented in Fig. 6 represent the most common and most used diagnostic procedures in diagnostic laboratories. Nevertheless, supplementary well-defined modules to mediate additional capabilities may be included in the future for proposed minimum standards for each type of RRML. In the minimal configuration, every module needs to include all necessary equipment and consumables for a predefined working duration to ensure adherence to minimum technical and logistic self-sufficiency requirements, as well as the required expertise to perform testing. In some situations, additional modules may be required in order to perform specific functions as determined by the nature of the response itself, and to allow for the scale-up of operations (Fig. 6 and Fig. 7). Additional large- or small-scale CRN modules may be deployed depending on the situation; customizable field research modules will be defined, standardized and depending on complexity, categorized as either basic or advanced.

Fig. 6. Example modules for configuring RRMLs for deployment



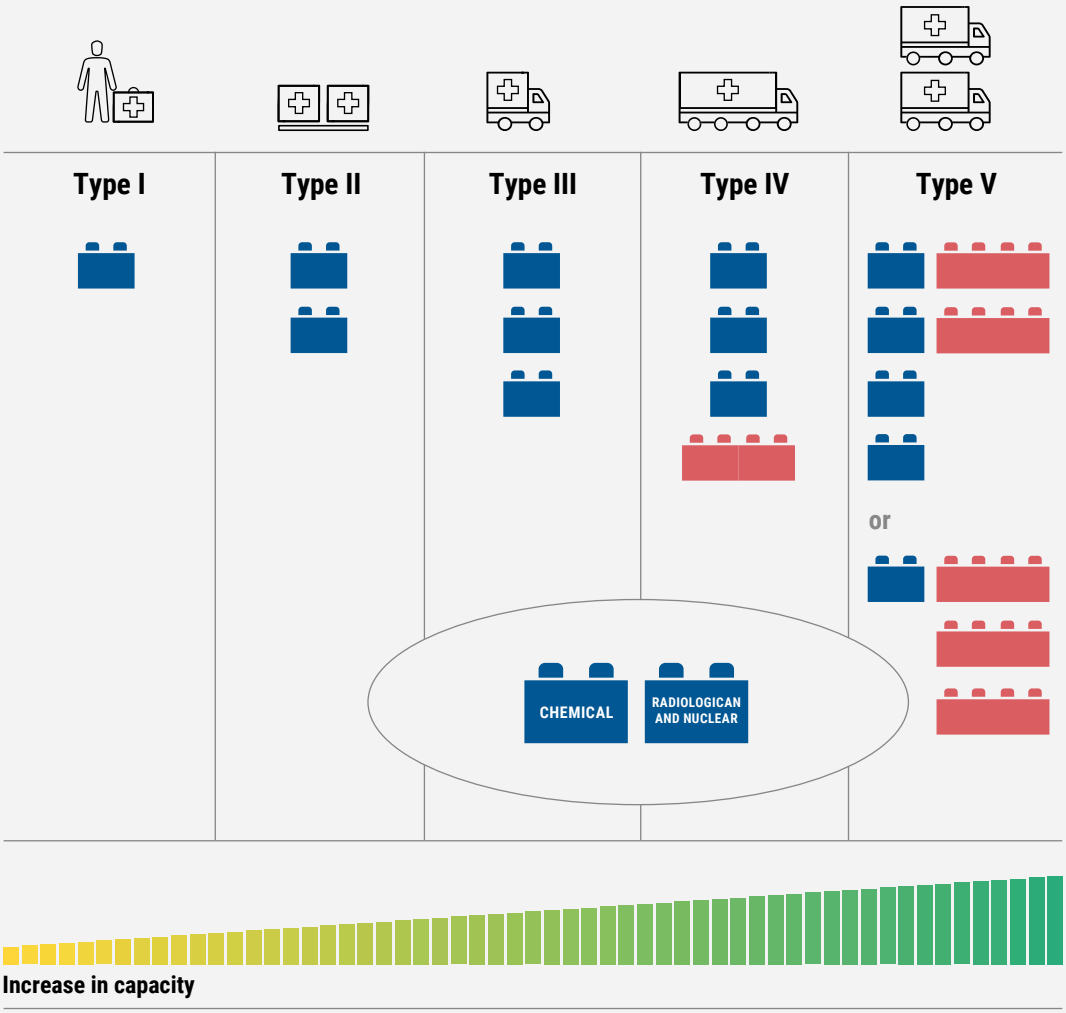
The modules also include the specific diagnostic or testing procedures that the RRMLs can perform. Different RRMLs will have the capability to perform a range of different procedures, but not all may be necessary in a given situation. This allows for flexibility in response, as additional modules can be added to RRMLs depending on the evolving dynamics of an incident. For example, a Type IV laboratory might focus on diagnostic PCR or ELISA diagnostics, but later add the capacity to perform HTS as a module during deployment upon request.

Single modules may be detached from higher RRML types and could be deployed as individual units. These units will be regarded as Type I RRMLs during deployment and will need to fulfil the complete spectrum of Type I RRML requirements, including biosafety and biosecurity precautions, QMS, LIMS and logistic measurements.

In addition, the modular approach has the potential to expand the capability for chemical testing and radiological and nuclear detection, for triage or the initial investigation of the source of the hazard.

© WHO/Jan Baumann

Fig. 7. Modular approach to minimal laboratory capabilities by RRML type



Generally speaking, the advantage of the modular approach is the increased scalability of RRMLs through the parallel deployment of additional modules of the same kind. Single modules may also be recognized and quality-managed as individual units. Table 1 describes the potential capacities of modules by type of RRML, and an overview of the RRML classification is in Annex 1.

Both capability and capacity of RRMLs increase from Type I to Type V. Lower types are able to handle a limited number of basic modules, whereas higher types can handle a greater number of modules. Additionally, RRMLs of Types IV and V are able to handle advanced modules, due to increased potential for architectural complexity and greater biosafety and biosecurity capabilities. Modules may be arranged in any number of combinations within a particular RRML, and multiple RRMLs may be deployed alongside one another within an incident. CRN components of different capabilities and capacities may also be deployed across the different types of RRMLs, but their operation will also depend on the needs of the situation. The forthcoming RMML standardization process will define this in detail.

Table 1. Estimated modular capacity of laboratory techniques by RRML type

Laboratory technique ▼	Indicated output per day ►				
	Type I	**Type II**	**Type III**	**Type IV**	**Type V**
qPCR	30–50	40–60	80–100	100–200	300–500
ELISA	100–200	200–300	300–400	500–600	800–1000
Rapid sequencing (kb)[a]	500–1500	500–1500	1000–2000	2000–3000	2000–3000
Microscopy I	10–25	20–40	30–50	50–70	100–200
Microscopy II	NA	15–30	30–50	50–70	100–200
Bacterial culture	NA	NA	NA	100–200	200–300
Blood culture[b]	NA	NA	NA	10–30	20–40
Clinical chemistry	10–20	25–50	25–50	50–75	>75
Environmental testing[c]	30–50	40–60	60–80	70–90	80–100
Animal models	NA	NA	NA	NA	5–10

[a] Calculation based on full-genome sequencing of Ebola

[b] Daily capacity is calculated according to start of culture breeding

[c] Capacity of environmental testing varies widely; these estimates are for water quality testing

Each type of RRML will have a different sample throughput, with up to a tenfold difference in capacity between Type I and Type V. However, the throughput of RRMLs is highly dependent on available resources, the number of different procedures requested and the size of the population served, as well as the type of RRML, so the figures presented are estimates and will vary across individual RRMLs and response activities.

DATABASE OF THE CAPACITIES OF RRMLs

Closing the information gaps would help develop a more comprehensive understanding of the RRML landscape. Developing a comprehensive RRML database to contain a complete and quantitative roster of global and regional rapid response capacities will provide WHO and other coordinating bodies with a better understanding of what exists and what is still needed. The RRML registration forms in Annex 2 and Annex 3 are designed to standardize and collect this information from partners.

It is in the interests of GOARN partners and all RRMLs to make this information available to WHO and other relevant partners. A consolidated repository of standardized RRML information has several benefits.

- **Decision-maker**s will have an understanding of what capacities already exist and what requires further development/strengthening. This information also provides a clearer understanding of what specifically can be offered to the affected countries and what kind of additional information should be requested from the emergency-affected countries. Based on these data, WHO or other coordinating structures could prioritize and request the deployment of specific types of RRMLs.

- **Affected countries** will better understand the existing global and regional RRML capacities (what to expect from WHO and other partners) and have the ability to modify their requests for support in a more defined and well-structured way to best meet their needs.

- **RRMLs** will have the ability to conduct more targeted responses and fast track deployments. The database will also provide teams with a better understanding of what is required in terms of strengthening RRMLs and aligning them with other rapid response capacities — interoperability, scalability and more.

To participate in GOARN, each RRML submits the forms in Annexes 2 and 3 for approval. Upon a request for WHO support, GOARN will align the response needs with the information provided by approved RRMLs and support their deployment and coordination. This will take into consideration the scale, location and localization of the event and associated conditions such as duration of deployment and speed.

A proposed algorithm to configure the RRML response to a request for support is in Annex 4. When a request arrives, information about the incident is collated from all available sources and used to inform what is required of the RRML. Then the requirements are crosschecked against the database to determine the appropriate type of RRML thus identifying partners with the capability and capacity to respond. This process may involve the deployment of combinations of multiple RRMLs in parallel to respond to needs on the ground.

ETHICAL CONSIDERATIONS

There are well-established international guidelines on ethical standards in global health, including how an organization should operate in an outbreak environment *(14,15)*. Additional standards should be adhered to regarding data collection and storage, particularly of sensitive information and patient confidentiality *(16)* and will be addressed in the LIMS standardization process.

In addition, RRML staff should be introduced to the applicable local laws and sociocultural rules of the location in which they will be operating, including participation in a cultural awareness briefing before deployment. It is also important to consider staff pre-deployment requirements for health *(17,18)*. This information will be facilitated by the standardization activities, namely a legislative analysis that will inform recommendations and content. Dependent on the mode of RRML activation, the briefing needs to be facilitated by the deploying organizations/institutions/countries or coordinating rapid response capacity bodies.

© Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor)

NEXT STEPS

This publication summarizes the classification of RRMLs as straightforward guidance is necessary for response partners during emergencies. The next steps in strengthening RRML activities follow the four pillars of the RRML Framework (Fig. 1), and will be further clarified through forthcoming standardization discussions.

Standards

This publication serves as the precursor to the subsequent RRML standardization process. Working groups will be coordinated for defining formal minimum RRML standards, as well as outlining the definitions of deployment mechanisms and potential for interoperability with other rapid response capacities. Within these working groups, participants will also conduct mapping exercises to have a comprehensive understanding of the RRML landscape, and the topics and workstreams discussed within this publication.

In addition to the quality and safety standards set during the forthcoming standardization of QMS, and biosafety and biosecurity, all RRMLs should seek to be in compliance with relevant international standards *(3,6–12)* and local circumstances in the same way that would be applicable to a conventional stationary laboratory in the home country. All RRMLs should be in compliance with the minimum set of RRML standards developed by WHO in collaboration with partners.

Coordination in emergencies

To ensure that all RRMLs that operate in the field can collaborate and coordinate with existing structures for emergency response, coordination mechanisms should be further discussed and aligned with those proposed by the Inter-Agency Standing Committee.

It is anticipated that in some situations RRMLs will work closely with other rapid response capacities (potentially as an integrated component or module of an emergency medical team facility) and should be ready to respond to the needs of the facility. This may mean defining the type of laboratory and modules required as requested by the needs of the specific rapid response capacities.

This process will be further discussed and developed during the development of minimum standards for RRMLs.

Workforce development

Workforce development is key to strengthening RRML teams and provides an opportunity to increase knowledge in times of non-emergency and emergencies, as well as to strengthen national capacities. Training for the RRML workforce will be developed according to the proposed standards and in line with existing trainings and requirements;

Staff deployed to an RRML should be appropriately trained in all relevant laboratory-related areas of action. This training will be defined during upcoming standardization discussions.

© WHO/Jan Baumann

REFERENCES[3]

1. Policy. In: WHO/Europe [website]. Copenhagen: WHO Regional Office for Europe; 2021 (http://www.euro.who.int/en/health-topics/emergencies/disaster-preparedness-and-response/policy).

2. Public Health Preparedness Capabilities: National Standards for Local and State Planning. Atlanta: Centers for Disease Control and Prevention; 2011.

3. Laboratory biosafety manual, third edition. Geneva: World Health Organization; 2004 (https://www.who.int/publications/i/item/9241546506).

4. Witt-Kushner J, Astles JR, Ridderhof JC, Martin RA, Wilcke B Jr, Downes FP et al. Core functions and capabilities of state public health laboratories: a report of the Association of Public Health Laboratories. MMWR Recomm Rep. 2002;51(RR-14):1–8.

5. EU Laboratory Capability Monitoring System (EULabCap). Report on 2016 survey of EU/EAA country capabilities and capacities. Stockholm: European Centre for Disease Prevention and Control; 2018.

6. Kessler H, Raggam R. Quality assurance and quality control in the routine molecular diagnostic laboratory for infectious diseases. Clin Chem Lab Med. 2012;50(7):1153–9. doi:10.1515/cclm-2011-0707.

7. ISO 15189:2012 Medical laboratories – Requirements for quality and competence. In: ISO [website]. Geneva: International Organization for Standardization; 2012 (https://www.iso.org/standard/56115.html).

8. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. In: ISO [website]. Geneva: International Organization for Standardization; 2017 (https://www.iso.org/standard/66912.html).

9. Laboratory quality management system: handbook. Geneva: World Health Organization; 2011 (https://www.who.int/ihr/publications/lqms/en/).

10. WHO European guidance on standards for infectious diseases laboratories. Copenhagen: WHO Regional Office for Europe; 2012 (https://www.euro.who.int/en/health-topics/communicable-diseases/influenza/publications/2012/who-european-guidance-on-standards-for-infectious-disease-laboratories).

3 All websites accessed on 27 January 2021.

11. OECD Guidelines for quality assurance in molecular genetic testing. Paris: Organisation for Economic Co-operation and Development; 2007.

12. WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites. Geneva: World Health Organization; 2016 (https://www.who.int/hiv/pub/toolkits/manual-external-quality-assessment-testing/en/).

13. Главный Государственный Санитарный Врач Российской Федерации. Постановление от 28 ноября 2013 года N 64. Об утверждении санитарно-эпидемиологических правил СП 1.3.3118-13 “Безопасность работы с микроорганизмами I-II групп патогенности (опасности)” (http://docs.cntd.ru/document/499061798).

14. Guidance for managing ethical issues in infectious disease outbreaks. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/250580).

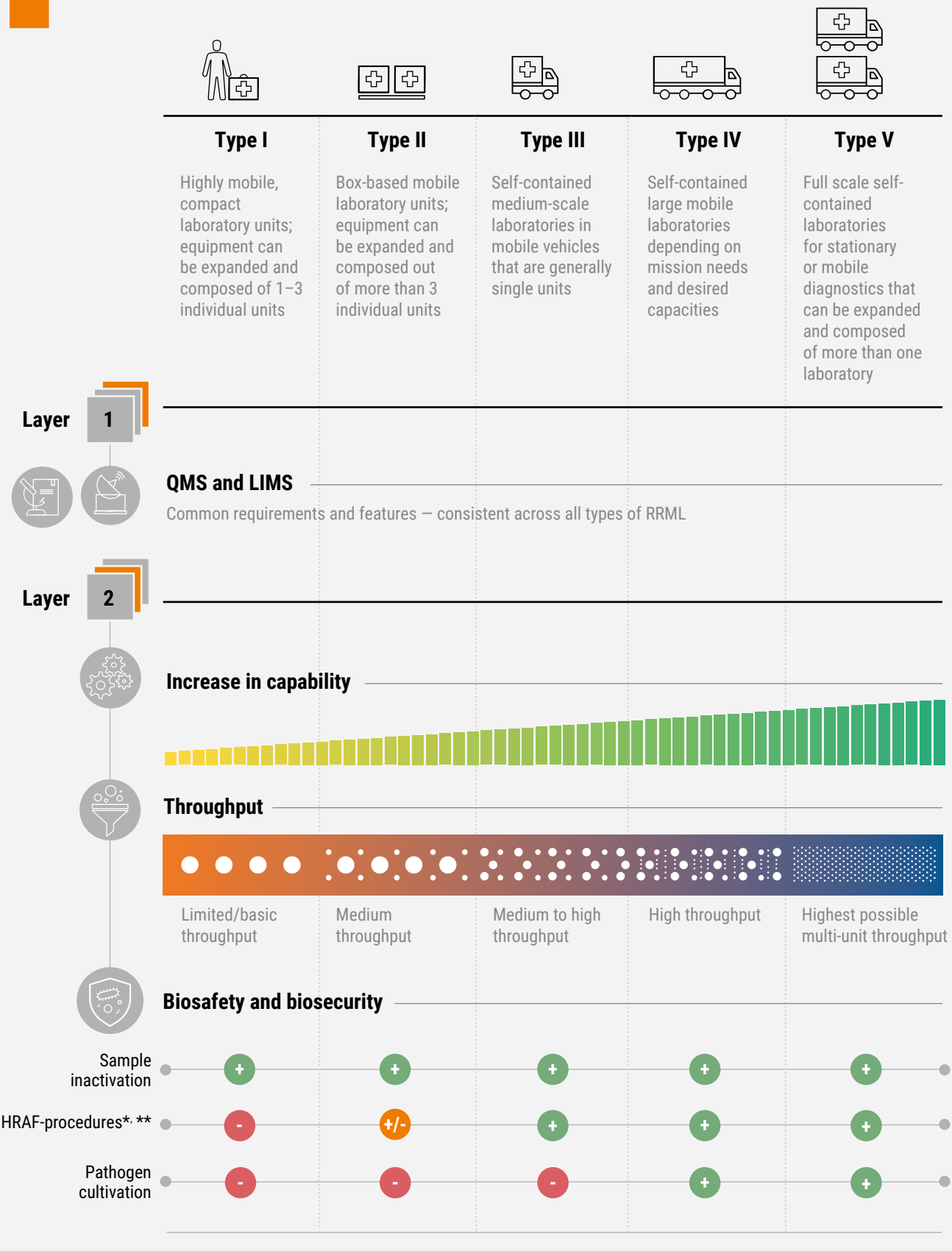
15. Global health ethics: key issues: global network of WHO collaborating centres for bioethics. Geneva: World Health Organization; 2015 (https://apps.who.int/iris/handle/10665/164576).

16. Medical records manual: a guide for developing countries. Manila: WHO Regional Office for the Western Pacific; 2006 (https://apps.who.int/iris/handle/10665/208125).

17. ERHMS Pre-deployment Health Screening for Emergency Responders. Atlanta: Centers for Disease Control and Prevention; 2017.

18. Table 4: Summary of WHO position papers – immunization of health care workers. Geneva: World Health Organization; 2020 (https://www.who.int/publications/m/item/table-4-who-recommendations-for-routine-immunization).

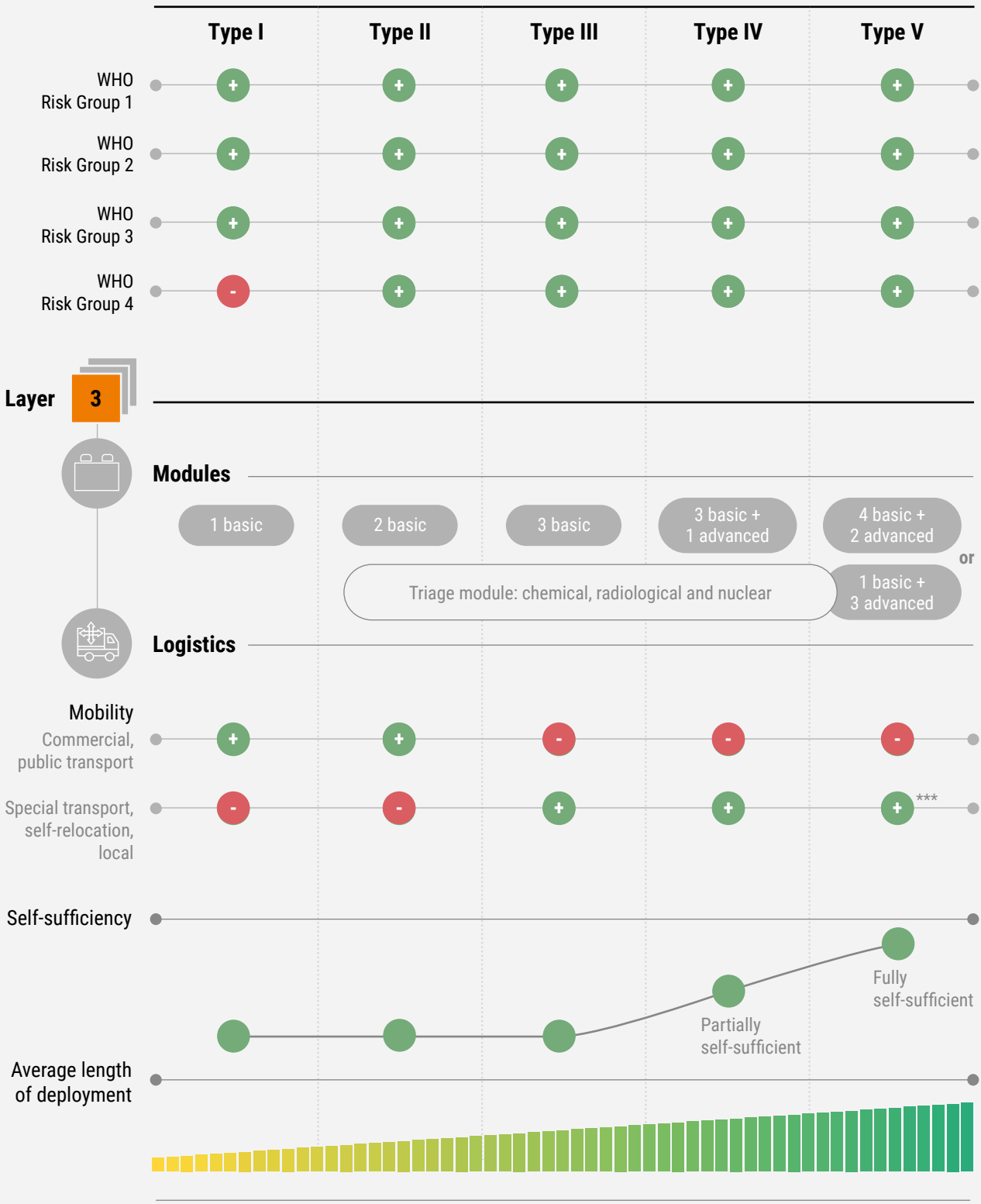
ANNEX I.



* AGP: aerosol-generating procedures; high-risk AGPs include centrifugation, homogenization, intensive mixing, ultrasonication, and handling large volumes or high concentrations of pathogens.

** High-risk AGPs may be engaged after implementation of quality-assurance.

OVERVIEW OF THE RRML CLASSIFICATION



*** Truck-based vehicles only.

ANNEX II.
REGISTRATION FORM FOR RRML CAPACITIES AND NEEDS

A. RRML Contact Details

Name of RRML holding institution or Member State	
Country	**Address**
National or Partner Focal Point	**Alternative Focal Point**
Name Address Phone Email	Name Address Phone Email

B. Overview – RRML Specifications

RRML Type[1]	
☐ Type I ☐ Type II ☐ Type III	☐ Type IV ☐ Type V
[1] For detailed type information please refer to "Guidance for Rapid Response Mobile Laboratory Classification"	
Diagnostic Modules *Please specify individual modules in detail using the "Diagnostic Module" form found in Annex III*	
☐ Diagnostic PCR ☐ Basic metabolic test module ☐ Light microscopy module ☐ Fluorescent microscopy module ☐ Bacterial culture module ☐ Environmental module	☐ Serology module ☐ Bacterial culture module ☐ Rapid sequencing module ☐ High-throughput sequencing module ☐ Blood culture module ☐ Others, please specify:

CBRN Triage Modules *Please specify individual modules in detail using the "Diagnostic Module" form found in Annex III*		
☐ C [chemical]	☐ R [radiological]	☐ N [nuclear]

Rapid Diagnostic Test Panel	
☐ Malaria *Please specify company* ☐ Influenza Virus A, B *Please specify company* ☐ Pregnancy *Please specify company*	☐ Dengue Virus *Please specify company* ☐ Hepatitis A, B *Please specify company* ☐ Hepatitis C *Please specify company* ☐ Others, please specify:
Sample Storage Capacity *Please specify the RRML sample storage capacity as total sample no.*	

C. Logistic Needs

Please specify only logistic needs that cannot be covered by the RRML and/or related organizations.

Facility Management	
☐ Shelter for RRML *Please specify dimensions* ☐ Laboratory furniture *Please specify amount* Chairs: Tables: Others: ☐ Vehicle *Please specify no. of personnel*	☐ Power supply *Please specify voltage and daily consumption* ☐ Fuel *Please specify amount* ☐ Waste management ☐ Water *Please specify weekly needs in litres*
Safety and Security	
☐ Medical support ☐ Security agents (laboratory, home)	☐ Evacuation (medical, safety)
Life Support	
☐ Water, drinking *Please specify dimensions* ☐ Hygiene *Please specify number of personnel* ☐ Social welfare	☐ Accommodation *Please specify number of personnel* ☐ Food, beverage *Please specify number of personnel*
Communication	
☐ Voice, mobile *Please specify number* ☐ Data, mobile	☐ Data, stationary

Supply Logistics	
☐ Supply chain, international ☐ Cold chain, international ☐ Procurement	☐ Supply chain, on-site ☐ Cold chain, on-site
Transport	
☐ Personnel, international *Please specify number of personnel* ☐ Equipment, international *Please specify dimensions (kg, tonnes)* ☐ Samples	☐ Personnel, on-site *Please specify number of personnel* ☐ Equipment, on-site *Please specify dimensions (kg, tonnes)*

D. Previous Deployments

D1. Has the RRML been deployed previously?
Also include trainings and exercises

☐ Yes

☐ No

D2. If yes, please indicate (last 5 years):

Deployment location (country)	**Deployment duration**	**Deployment mechanism** (e.g. bilateral/ GOARN)	**Objective** (outbreak/training/ simulation exercise, capacity development)

D3. Indicate the average time required to deploy the RRML.
The time interval from official deployment decision to country arrival.

☐ 1–2 days ☐ 5–10 days ☐ > 15 days

☐ 2–5 days ☐ 10–15 days

D4. Indicate the average time required for RRML setup at deployment location.
Including RRML installation and diagnostic test run.

☐ < 1 day ☐ 2–3 days ☐ > 6 days

☐ 1–2 days ☐ 4–6 days

E. RRML Personnel

E1. Staff Capacity

Personnel Number	
Personnel per RRML rotation *in field*	
Total staff capacity	
Team lead staff	
Laboratory staff	

E2. Specify functional roles covered by deployed personnel.

- ☐ Technical/Laboratory expert
- ☐ Public relations
- ☐ First aid
- ☐ Medical doctor
- ☐ Others, please specify:
- ☐ Team leader
- ☐ Informatics
- ☐ Diagnostic expert

E3. Please indicate which content is incorporated into personnel training.

- ☐ Diagnostic procedure
- ☐ Public relations
- ☐ First aid
- ☐ Mental preparedness
- ☐ Others, please specify:
- ☐ Documentation (LIMS)
- ☐ Communication in the field
- ☐ Troubleshooting
- ☐ Social/Cultural awareness

E4. Please indicate the provided post-deployment care by your institution

- ☐ Medical guidance
- ☐ Immediate experience questionnaire
- ☐ Psychological assistance
- ☐ Others, please specify:
- ☐ Communication of behaviour policy
- ☐ Follow-up experience questionnaire

ANNEX III.
REGISTRATION FORM FOR RRML DIAGNOSTIC MODULES

Please complete individual forms for each diagnostic module. A diagnostic module is a framed test procedure including diagnostic device, related consumables and the expertise to perform a given test.

Name RRML Organization

Module Name

Module Size

☐ Basic

☐ Advanced

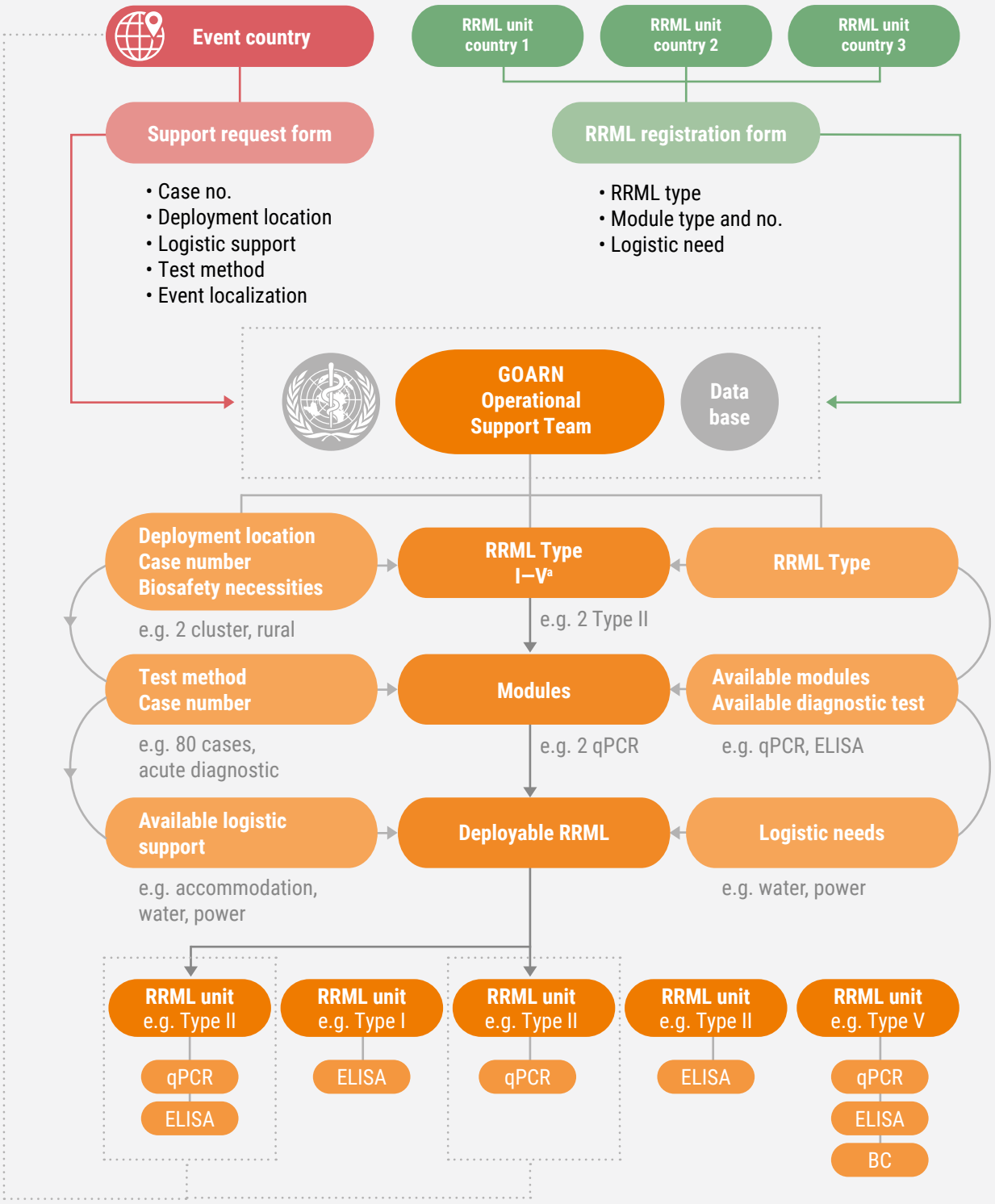
Short Description

Diagnostic Target Organisms

Organism/Pathogen	Detection limit *(not needed for commercial)*	Company name *(non commercial, in-house)*

Daily Test Capacity

ANNEX IV. DECISION TREE FOR CONFIGURING RRMLs



[a] For a detailed classification refer to Annex 1.
BC: blood culture.

NOTES

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Kazakhstan
Kyrgyzstan
Latvia
Lithuania
Luxembourg
Malta
Monaco
Montenegro
Netherlands
North Macedonia
Norway
Poland
Portugal
Republic of Moldova
Romania
Russian Federation
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
Turkey
Turkmenistan
Ukraine
United Kingdom
Uzbekistan

ISBN: 9789289054928

ISBN 978-92-890-5492-8
9 789289 054928

World Health Organization
Regional Office for Europe
UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark
Tel: +45 45 33 70 00
Fax: +45 45 33 70 01
Email: eurocontact@who.int
Website: www.euro.who.int