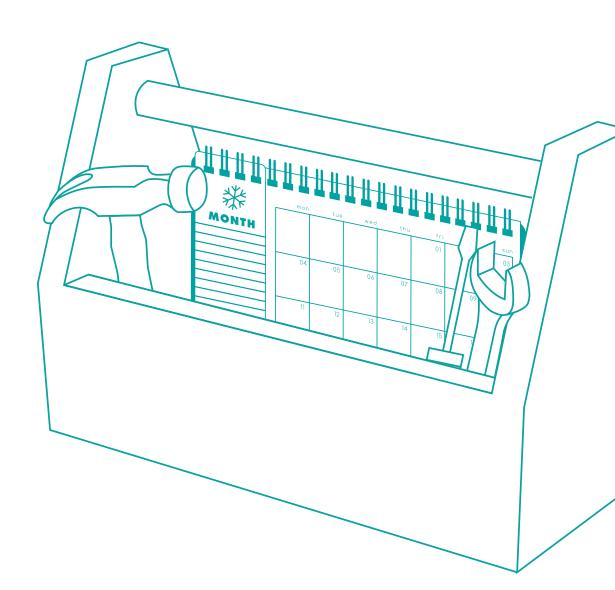
HOW TO DEVELOP A REPAIR AND MAINTENANCE SYSTEM FOR COLD CHAIN EQUIPMENT

March 2017





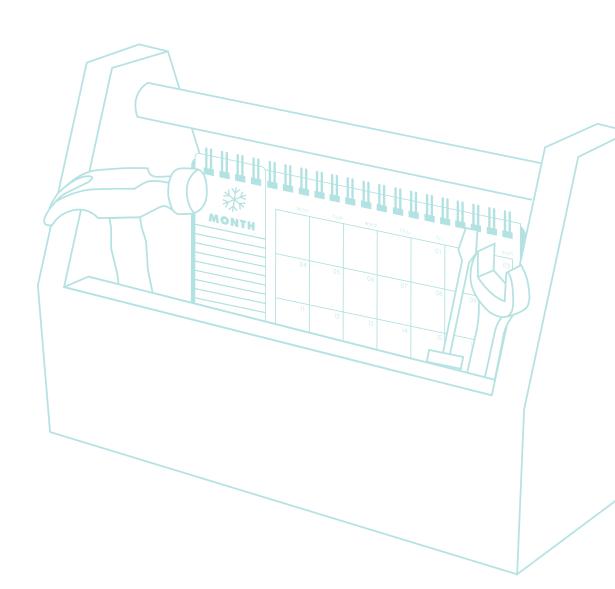
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Printed in Switzerland.

Design and layout by Paprika (Annecy, France)

Acknowledgements

This document was developed by the Expanded Programme on Immunization of the World Health Organization (WHO) Department of Immunization, Vaccines and Biologicals. The following individuals contributed to the production of this document and their inputs are acknowledged with sincere gratitude.

Independent consultants: James Cheyne, Ticky Raubenheimer

John Snow, Inc. (JSI): Ousmane Dia

PATH: Debra Kristensen, Joe Little, Sophie Newland, Joanie Robertson

United Nations Children's Fund (UNICEF): Dmitri Davydov, Serge Ganivet, Dereje Haile, Hailu Makonnen Kenea, Adama Sawadogo, Benjamin Schreiber, Teshome Yemamu

WHO: Oleg Benes, Diana Chang Blanc, Paul Colrain, Isaac Gobina, Moussa Harou, Anna-Lea Kahn, Souleymane Kone, Patrick Lydon, Denis Maire, Nasrin Musa, Nora Rodriguez

How to use this module

This module of the WHO Vaccine Management Handbook (VMH) is a component of the World Health Organization/United Nations Children's Fund Effective Vaccine Management (EVM) Initiative. The handbook is written for decision-makers at national and subnational levels; its purpose is to provide technical advice on key topics related to immunization logistics to help countries develop and refine national policies. For more detailed guidance on specific operational activities, readers should refer to the EVM model standard operating procedures.¹

Advice in the VMH generally conforms to the guidance on good storage and distribution practice given in WHO Technical Report Series, No. 961, 2011, Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products.²

¹ The model EVM standard operating procedures (SOPs) manual (PDF) and individual generic SOPs (Word) that may be adapted to create country-specific SOPs are available for download at: http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html, accessed 15 June 2016.

² WHO guidelines describing the principal requirements for the safe storage and distribution of time- and temperature-sensitive pharmaceutical products (TTSPPs) are available at: http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf, accessed 15 June 2016.

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Abbreviations

Expanded Programme on Immunization (WHO) EPI EVM Effective Vaccine Management IPM inspection and preventive maintenance LED light-emitting diode long-term arrangement LTA PQS performance, quality and safety (WHO) Supply Division (UNICEF) SD SOP standard operating procedure UNICEF United Nations Children's Fund Vaccine Management Handbook VMH WHO World Health Organization

Glossary

After-sales service: The *preventive maintenance* or *repair* services offered by an equipment manufacturer or supplier, provided during or after a *warranty period*.

Clinical engineer: A trained professional who supports and advances patient care by applying engineering and managerial skills to medical equipment.

Clinical engineering team: Staffed with engineers and technicians, this department is responsible for the management, maintenance and *repair* of medical equipment. This department or team may be referred to by a wide variety of names, including biomedical engineering department or medical equipment management unit.

Cold chain equipment: Equipment used to store and transport temperature-sensitive products at the proper temperature during each stage of the supply chain.

Cold chain equipment inventory: A record of the quantities, types and characteristics of the *cold chain equipment* deployed in a country or other administrative unit.

Commissioning: A series of tests and adjustments performed to check whether, and to ensure that, new equipment is functioning correctly and safely before use.

Corrective maintenance: A process to restore the physical integrity, safety and/or performance of a device after a *failure; corrective maintenance* covers all activities undertaken after equipment has broken down. This type of maintenance is typically not anticipated and is urgent in character. *Corrective maintenance* and unscheduled maintenance are regarded as equivalent to the term *repair*, which is used in this module.

Decommissioning: The process of removing cold chain equipment from routine use permanently when it fails to maintain desired temperatures or is beyond *repair*. This process includes removal of equipment from the health facility and the equipment inventory. Final disposal should be arranged according to the prevailing regulations.

Failure: The condition of not meeting the intended performance or safety requirements, and/or a breach of physical integrity. A *failure* is corrected by *repair* and/ or calibration.

Holdover time: The time in hours during which all points in the vaccine compartment of a vaccine refrigerator remain at less than +10°C, at the maximum ambient temperature

of the temperature zone for which the appliance is rated, after the power supply has been disconnected. For vaccine freezers, the *holdover time* is the time in hours during which the vaccine compartment remains at less than -5°C.

Ice-lined refrigerator: A compression-cycle refrigerator with an internal lining surrounding the storage that is filled with ice, cold water or other coolant. When the electricity supply fails, the ice, cold water or coolant keeps the refrigerator cool for a minimum of 20 hours without power.

Outsourcing: The practice of sourcing processes from third parties to fulfil various roles in the supply chain, such as maintenance, transportation, warehousing or information management.

Parastatalorganization: Afully or partially government-owned or government-funded organization. These organizations often function through a board of directors, similar to those of private corporations; however, the government retains control over the *parastatal organization*.

Planned maintenance: See preventive maintenance.

Preventive maintenance: Procedures that reduce the likelihood of equipment *failure* and extend the life of equipment (for example, calibration, part replacement, lubrication or cleaning). *Preventive maintenance* activities are conducted in a systematic manner before equipment *failure* – based on a schedule set by time, distance or cycles of operation. *Preventive maintenance* is sometimes referred to as *planned maintenance*.

Repair: See corrective maintenance.

Service-level agreement: A negotiated agreement between a customer and a service provider that defines the common understanding about materials or service quality specifications, responsibilities, guarantees and communication mechanisms. It can be either legally binding or an informal agreement. The *service-level agreement* may also specify the target and minimum level performance, operation, or other service attributes.

Standard operating procedure: Detailed, written and/or visual instructions designed to ensure that a specific task or function is carried out in a consistent and uniform manner.

Warranty period: A time period set forth in a written purchasing contract in which a manufacturer or supplier guarantees to *repair* or replace equipment if a defect is identified.

->> 1. Introduction

This module introduces the policy, technical, material, budget and management requirements of an effective cold chain equipment maintenance and repair system.

Successful maintenance and repair systems require coordinated leadership from multiple departments in the ministry of health to ensure reliable and rapid access to qualified technicians, tools and spare parts at all levels of the health system.

Development of effective maintenance and repair systems for cold chain equipment begins at procurement, with the setting of equipment standards, and mandatory inclusion of spare parts, user training and technician support in tenders. In addition, national-, subnationaland facility-level equipment maintenance plans must be established along with the associated multiyear budgets.

While it is difficult to develop, fund and implement an effective cold chain equipment maintenance and repair system, these systems are essential to ensuring that all children and other members of the population have access to vaccines that are potent, and these systems ultimately contribute to a cost-effective immunization programme.

Analysis based on data from 57 Gavi-eligible countries estimated that approximately one fifth of facilities have no cold chain equipment (such as refrigerators, freezers or cold rooms); one fifth have equipment that does not work; and more than two fifths have equipment with significant limitations, such as a high freezing risk and/or the need for expensive gas or kerosene.³ The results of this analysis are shown in Figure 1 to the right.

When Effective Vaccine Management (EVM) assessments results were analysed in 2015, only 8% of the assessed countries met the WHO global standard for preventive maintenance. In all assessed countries, preventive maintenance scores become progressively weaker from subnational to district to service delivery levels.⁴ Immunization supply chain systems without effective preventive maintenance programmes at all levels of the vaccine supply chain can seriously jeopardize the goals of an immunization programme and reduce its efficiency.

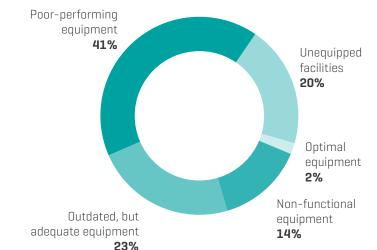


Figure 1 – Cold chain equipment status in 57 low- or lower-middle-income countries (2014)

1

Studies suggest that only one third of equipment problems require the input of specialized technicians, approximately one third of all equipment problems are caused by operator or installation errors, and another one third of equipment problems require only simple repair that can be carried out by facility-based staff.⁵ These statistics reinforce the importance of establishing a maintenance and repair system that builds the capacity of equipment users to correctly use and maintain equipment, verifies the proper installation and commissioning of new equipment, and quickly mobilizes specialized technicians, tools and spare parts when and where necessary.

This Vaccine Management Handbook (VMH) module introduces the recommended components of a national cold chain equipment maintenance and repair system and outlines what needs to be included in a national equipment maintenance plan and budget. A key message of this module is that managers, technical staff and immunization providers must work together to plan, implement and sustain an effective cold chain equipment repair and maintenance system.

⁵ Temple-Bird C, Kaur M, Lenel A, Kawohl W. 'How to Manage' Series for Healthcare Technology. Guide 5: How to Organize the Maintenance of Your Healthcare Technology. Lewes: Ziken International Consultants Ltd; 2005:38. Available at: http://www.who.int/management/resources/equipment/en/ index1.html, accessed 15 June 2016.

³ Bill & Melinda Gates Foundation. Analysis based on data from 57 Gavi-eligible countries. 2014. Cited by: PATH, Gavi, the Vaccine Alliance, Bill & Melinda Gates Foundation, John Snow, Inc., VillageReach. Next-generation immunization supply chains are needed to improve health outcomes. Seattle (WA): PATH; 2015. Available at: http://www.path.org/vaccineresources/details.php?i=2116, accessed 15 June 2016.

⁴ Effective Vaccine Management (EVM) global data analysis 2009–2014. Geneva: WHO; 2015. Available at: http://www.who.int/immunization/ programmes_systems/supply_chain/evm/en/index4.html, accessed 15 June 2016.

1.1 Objectives

The specific objectives of this module are to:

- a. describe the role of an effective equipment maintenance and repair system in a successful national immunization programme;
- b. reinforce the importance of a national cold chain equipment maintenance policy, plan and multiyear budget; and
- c. describe the contents of a cold chain maintenance plan and budget.

1.2 Target audience

This module is intended for Expanded Programme on Immunization (EPI) managers, logisticians, cold chain managers and clinical engineering teams concerned with running an effective maintenance and repair system, as well as ministry of health decision-makers and all partners responsible for:

- a. implementing and maintaining an effective and strong vaccine supply chain;
- b. budgeting for, procuring for, monitoring and managing health system infrastructure;
- c. developing health system policies and budgets;
- d. managing immunization services at health centres and health posts;
- e. managing equipment maintenance service providers, supplies and stock;
- f. developing, updating and distributing standard operating procedures (SOPs) and job aids to communicate, support and standardize best vaccine management practices; and
- g. installing, commissioning, maintaining, repairing, decommissioning and operating cold chain equipment.

1.3 Definition of maintenance

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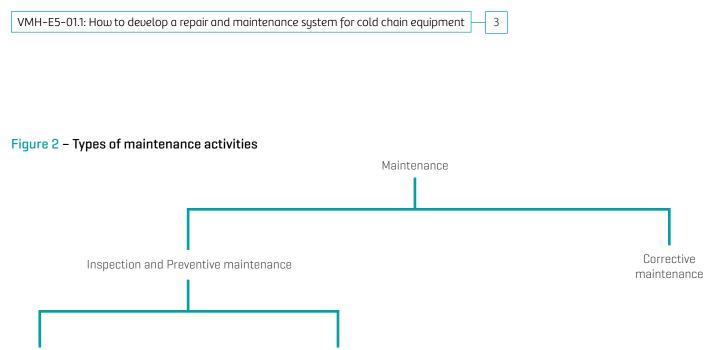
The primary goal of an equipment maintenance and repair system is to eliminate or to avoid unnecessary or unplanned equipment downtime due to failure. Maintenance activities can be divided into two major categories: 1) inspection and preventive maintenance (IPM) and 2) corrective maintenance, as shown in Figure 2 and described in the WHO Medical Device Technical Series.⁶

IPM activities are scheduled to ensure equipment functionality and prevent breakdowns or failures. Inspections verify proper functionality and safe use of a device. Preventive maintenance activities are scheduled to extend the life of a device and prevent failure. Examples of these activities are calibration, part replacement, lubrication and cleaning. Inspection can be a stand-alone activity or can be conducted along with preventive maintenance to ensure functionality. In contrast, corrective maintenance and unscheduled maintenance are performed after there has been a failure of equipment. They are regarded as equivalent to the term *repair*.

Implementing a preventive maintenance strategy will result in lower repair costs and fewer unexpected equipment failures. In contrast, a maintenance system that is only able to react to equipment failures will probably not only result in higher total cold chain equipment costs but will also put vaccine potency and availability at risk.

This module is intended to help national immunization programmes and ministry of health agencies develop a cold chain equipment maintenance and repair system that will help prevent many equipment failures and lower the total maintenance costs of the immunization supply chain and logistics system.

⁶ These definitions and an overview of medical equipment management can be found in the WHO Medical Device Technical Series module on medical equipment maintenance programmes, available at: http://apps.who.int/ medicinedocs/documents/s21566en/s21566en.pdf, accessed 15 June 2016.



Inspection

Preventive maintenance

• 2. Establishing a maintenance and repair system

An effective cold chain equipment maintenance and repair system relies on a commitment to the development and distribution of SOPs, active monitoring and supervision programmes, and access to trained staff who have the necessary transport and materials to maintain and repair cold chain equipment. These maintenance and repair systems help ensure that vaccines are kept at safe storage temperatures and that they are accessible where and when needed to provide all immunization services.

2.1 Standard operating procedures

SOPs describe important activities to ensure that anyone can perform those activities correctly and consistently. SOPs are essential for capturing institutional knowledge and for training new employees. In addition, they help ensure that work procedures are conducted to a consistent quality. SOPs can also establish a legal compliance requirement or serve in a quality assurance role.

An SOP is specific to a single task or a very limited group of tasks; it is not a general planning or policy document or a general description of a large group of tasks. An SOP should be focused and not contain material that is irrelevant to the target audience. For example, an SOP for maintaining provincial-level refrigerators should only include information about the particular type(s) of refrigerators used at the provincial level; details about kerosene, gas or solar refrigerators should not be included if only mainselectric icelined refrigerators are used at the provincial-level facilities.

An SOP should contain the following sections:

- **Policy statement:** Identifies the policy it is intended to support.
- **Objective:** Defines what activities it covers and when the SOP applies.
- **Responsibility:** Identifies the position of the person responsible for carrying out the activity.
- Associated materials and equipment: Lists any associated SOPs, standard forms and other reference documents. If specific equipment is needed, it lists that equipment.
- **Procedure:** Clearly describes the procedure as a series of steps using diagrams and photographs where relevant.
- **Document revision and distribution history:** Records the distribution of the SOP and all its revisions. Superseded versions should be withdrawn, from both the point of development and the point of use.

International and national standards referenced in support of equipment maintenance SOPs may include ISO (International Organization for Standardization) 9001 or local regulatory requirements implemented by the national regulatory authority. The World Health Organization (WHO) performance, quality and safety (PQS) equipment performance standards and the requirements of donor agencies such as Gavi, the Vaccine Alliance, and the United Nations Children's Fund (UNICEF) may also apply.

Example SOP topics include:

• installation of specific cold chain equipment;

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- operation of cold chain equipment;
- regular preventive maintenance of cold chain equipment;
- proper disposal of equipment at end of life;
- collection of an inventory of equipment.

Since SOPs must be tailor-made for each site and according to individual responsibilities, national immunization programmes or ministries of health should develop model SOPs with the requirement that subnational- or facility-level managers adapt, finalize and continuously update them at their facilities. The EVM Initiative website provides examples of model SOPs that national EPI teams can adapt.⁷

Note: As appropriate, a job aid may be distributed to equipment users that highlights key points of their required daily, weekly and monthly maintenance tasks to reinforce the SOPs. Annex 1 provides a sample job aid template and Annex 2 provides a sample maintenance checklist.⁸

2.2 Reporting systems

The maintenance and repair of cold chain equipment should comply with policies, work plans, service-level agreements and SOPs. Compliance monitoring requires a reporting system that registers all maintenance and repair services and tracks equipment performance.⁹

⁷ The EVM standard operating procedures (SOPs) can be downloaded as a set from the following webpage: http://www.who.int/immunization/ programmes_systems/supply_chain/evm/en/index2.html, accessed 15 June 2016.

⁸ Ajob aid on preventive maintenance is included in the Handbook for vaccine and cold chain handlers, 2nd edition (2016), developed by the Ministry of Health and Social Welfare of India, available at the following webpage: http://www.nccvmtc.org/PDF1/Unicef_Cold_Chain_Handlers_2016.pdf, accessed 15 June 2016.

⁹ Computerized maintenance management system. Geneva: WHO; 2011. Medical Device Technical Series. Available at: http://apps.who.int/iris/ bitstream/10665/44567/1/9789241501415_eng.pdf, accessed 15 June 2016.

Reporting systems will help immunization programmes:

- verify that maintenance services are performed as required;
- build equipment maintenance and performance histories to help managers predict equipment performance problems;
- identify common user errors that should be addressed with supportive supervision and training;
- track and order spare parts;
- plan equipment replacement schedules; and
- demonstrate the cost-effectiveness of maintenance services.

2.2.1 Equipment inventories

An accurate equipment inventory provides immunization programme managers and maintenance teams with important information about existing cold chain equipment appliances, including their functional status, age, location and net storage capacity.^{10,11} This cold chain equipment inventory helps technicians plan repair activities and manage spare parts. Cold chain managers can use these data to plan cold chain equipment purchases. Equipment inventories also make contingency planning easier, helping to identify alternative storage locations when needed due to equipment failure.

By combining maintenance and repair service data with an equipment inventory, maintenance technicians and cold chain managers can:

- anticipate when equipment is likely to need replacement;
- determine which facilities need or will need additional cold chain equipment; and
- ascertain which equipment needs maintenance or repair, where it is located and what spare parts and tools are needed.

An equipment inventory is a listing of the key details of each cold chain equipment appliance. It also contains relevant facility details, including energy availability, catchment population and types of immunization services. Using an equipment inventory as the foundation of a reporting system for equipment maintenance and repair systems also makes it easier to improve the accuracy of the equipment inventory data and to keep the data current. Ideally, an equipment inventory must be updated regularly; at minimum the equipment functional status must be updated on a monthly basis.

2.2.2 Maintenance and repair records

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Maintenance and repair records contain information about each service performed on a piece of cold chain equipment, including make, model and location of the specific device, the date and time of the service provided, the name and title of the person who performed the service, a description of what was done, a list of parts installed in the course of the service, the status of the device after the service was completed, comments on the service performed or further service needed, the cost of the service (if applicable), and a signature of the equipment owner acknowledging that the service was received. Photos can also be part of the record. Wherever possible, this service record should be linked to the national cold chain equipment inventory through the use of a unique identifier for the equipment item that appears on both the maintenance record and the inventory.

Analysis of equipment maintenance and repair records can help an immunization programme identify equipment models that require less maintenance and repairs, and have a longer economically viable lifetime. These models may be established as standard equipment models to help reduce the technical, procedural and training requirements of the equipment maintenance system. Analysis of these records can identify:

- common problems by model;
- spare parts most frequently used by model;
- number of repair or maintenance activities performed in a month by administrative area;
- service histories of individual devices;
- equipment operator training needs; and
- cost-effectiveness of equipment maintenance and repair services.

The maintenance team can use the maintenance and repair records to estimate the consumption of spare parts in order to predict order quantities and timing, track spare parts, prepare annual budgets and customize equipmentuser training materials. Records of the daily temperature monitoring of equipment should be included as part of the overall maintenance records for each piece of equipment.

When a specific model or shipment of cold chain equipment is found to have a defect or higher-than-expected rate of repair, it should be reported to UNICEF Supply Division (SD) and the WHO PQS Secretariat.^{12,13} Equipment manufacturers

¹⁰ Introduction to medical equipment inventory management. Geneva: WHO; 2011: Chapter 9. Medical Device Technical Series. Available at: http://apps. who.int/medicinedocs/documents/s21565en/s21565en.pdf, accessed 15 June 2016.

¹¹ Mid-level management course for EPI managers: Module 8. EPI cold chain management. Geneva: WHO Regional Office for Africa; 2004. Available at: http://www.afro.who.int/index.php?option=com_docman&task=doc_ download&gid=6567, accessed 15 June 2016.

¹² To submit complaints, fill out and send Annex 1 of the General Procurement Guidelines to the UNICEF SD cold chain team (sd.coldchain@unicef.org). Guidelines can be found at: http://www.unicef.org/supply/files/General_ Procurement_Guideline_Oct_28_2014.pdf, accessed 15 June 2016.

¹³ To report product defects for any product found in the WHO PQS Catalogue or website, please submit the user feedback form available at: http://

or local representatives should also be informed, in particular, when faults are identified within the warranty period.

2.2.3 Spare parts stock records

Spare parts stock control systems help managers dispatch repair technicians with the right spare parts and help them reorder these parts in the right quantity, when needed.¹⁴

Spare parts record-keeping procedures should include the following data:

- part description (name);
- stock (inventory) number;
- manufacturer's name, serial and part number;
- link to equipment models;
- minimum stock level;
- current stock level;
- part storage location;
- price and date purchased.

A number of factors will affect how often to order spare parts, including:

- rate of use of each part (estimated from past experience and records);
- level of criticality to operation;
- procurement lead time for each item;
- frequency of ordering;
- dry storage capacity;
- cost of each part.

Managers should analyse spare part stock records to identify which spare parts are most quickly consumed. Forward planning will ensure that these parts are available when and where needed.¹⁵

In many countries, the problem of obtaining replacement parts at a reasonable cost and in a timely manner can be substantial. WHO PQS requires that consumables and spare parts be supplied by the manufacturer at the time of procurement for walk-in cold rooms and

apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/feedbackform.aspx, accessed 15 June 2016.

walk-in freezer rooms¹⁶ For compression refrigerators and freezers, WHO PQS requires that an itemized list of spare parts be provided, including part numbers to facilitate ordering.

2.2.4 Temperature monitoring

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To maintain vaccine quality, temperatures should be continuously monitored throughout the supply chain¹⁷ Monitoring of temperature data can help verify that cold chain equipment is functioning as needed to protect vaccine potency, and, when out-of-range temperatures are detected, enable corrective action to be taken immediately.

To support effective maintenance systems, temperature monitoring data should be integrated into an information system that also includes cold chain equipment inventory, spare part stock control, and service history data. A computerized maintenance management system can facilitate decision-making by technicians, provide evidence on the impact of investments in effective maintenance systems, monitor equipment performance over time, and demonstrate compliance with good storage and distribution practices.¹⁸

2.3 Emergency situations and contingency plans

Due to the temperature sensitivity of vaccines, any interruption to the normal functioning of cold chain equipment is an emergency situation. Emergency situations are typically due to either power failures or equipment failures. The risks from these emergencies can be minimized by developing a contingency plan and ensuring that all relevant staff are aware of the plan.

To develop a practical contingency plan, health centre staff, technicians and managers must:

- develop a list of what to check when equipment failure is identified (for example, equipment does not start, there is no cooling, or the temperature is outside the +2°C to +8°C range);
- assess equipment holdover time;

¹⁶ WHO. PQS performance specification: Cold rooms and freezer rooms. Geneva: WHO; 2009:4.2.21–4.2.22. Available at: http://www.who.int/ immunization_standards/vaccine_quality/pqs_e01_cr_fr01_2_perfspec. pdf, accessed 15 June 2016.

¹⁷ More information can be found in the How to monitor temperatures in the vaccine supply chain module of the VMH Handbook. Available at: http:// apps.who.int/iris/bitstream/10665/183583/1/WHO_IVB_15.04_eng.pdf, Accessed 15 June 2016

¹⁸ More information can be found in: Computerized maintenance management systems. Geneva: WHO; 2011. WHO Medical Device Technical Series. Available at: http://apps.who.int/iris/bitstream/10665/44567/1/9789241501415_eng.pdf, accessed 15 June 2016.

¹⁴ Temple-Bird C, Kaur M, Lenel A, Kawohl W. 'How to Manage' Series for Healthcare Technology. Guide 5: How to Organize the Maintenance of Your Healthcare Technology. Lewes: Ziken International Consultants Ltd; 2005. Available at: http://www.who.int/entity/management/organize_ maintenance_healthcare.pdf, accessed 15 June 2016.

¹⁵ UNICEF Cold Chain Support Package, Procurement Guidelines, available at: http://www.unicef.org/supply/files/General_Procurement_Guideline_ Oct_28_2014.pdf, accessed 15 June 2016.

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- identify a suitable alternative vaccine storage location;
- secure needed resources to use the alternative location;
- identify clear roles and responsibilities for the people who will implement the contingency plan;
- inform all staff of the plan and of the requirements and activities that may be necessary during an emergency, and train them accordingly;
- document contingency plan actions in an SOP; and
- periodically update contingency plans and contact information, and refresh training of staff.

Posters or job aids should be developed and attached to refrigerators or walls nearby and should provide clear instructions in the local language about what to do when cold chain equipment is not working due to breakdowns or interruptions in electricity supply. Annex 3 provides a template for a vaccine storage contingency plan.

3. Requirements of equipment maintenance systems

Cold chain equipment maintenance can be broadly categorized as either preventive maintenance or corrective maintenance (*repair*), as shown in Figure 2 above.¹⁹

Preventive maintenance is defined as procedures that reduce the likelihood of equipment *failure* and extend the life of equipment, for example calibration, routine part replacement, lubrication or cleaning. Preventive maintenance activities are conducted in a systematic manner before equipment *failure*, based on a schedule set by time, distance or cycles of operation. Preventive maintenance is sometimes referred to as planned maintenance.

Inspection and preventive maintenance is conducted even when the equipment is performing well, and it includes routine temperature monitoring of the vaccine storage compartment to help identify when repair is necessary. Inspection verifies proper equipment functionality and safe use and can be a stand-alone activity, such as routine temperature monitoring, or conducted as part preventive maintenance to ensure proper functionality.

Corrective maintenance or repair is a process to restore the physical integrity, safety and/or performance of a device after a *failure*; corrective maintenance covers all activities undertaken after equipment has broken down. This type of maintenance is typically not anticipated and is urgent in character. Corrective maintenance and unscheduled maintenance are regarded as equivalent to the term *repair*, which is used in this module.

Most equipment failure can be avoided with routine preventive maintenance. If cold chain equipment is connected to a highquality power supply, there is good ventilation surrounding the equipment, and users routinely clean and defrost the equipment, then the equipment can function for years without the need for specialized technical maintenance or repair. On the other hand, some refrigerator equipment components, including compressors and controllers, may break through no fault of the user. In this case, specialized repair services will be required.

3.1 Policy framework

An equipment maintenance policy informs all departments of the ministry of health and public and private immunization providers that they must plan, budget, implement and manage equipment maintenance and repair activities. It communicates the need to establish national-, subnationaland facility-level equipment maintenance plans and multiyear budgets, including funding and staff needed to maintain and manage a spare parts inventory.

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If an equipment maintenance policy does not exist, the ministry of health should implement a participatory approach to build the support of required stakeholders. This policy development process should include a directive from senior management that:

- communicates the need for a cold chain equipment maintenance system;
- defines the scope and purpose of the equipment maintenance policy;
- identifies the departments and groups of staff that should be involved;
- estimates the policy development time requirements;
- quantifies the projected cost implications; and
- clarifies high-level commitment to a participatory policy development approach.

A national cold chain equipment maintenance policy could include:

- the role of the ministry of health clinical engineering team;
- the role of the EPI cold chain team;
- officially recognized equipment maintenance organizations, including university and parastatal technical institutes and the private sector;
- certification requirements and processes for maintenance service providers, both private and public;
- adherence to international or national technical standards;
- requirements for all equipment donations;
- requirements for maintenance plans and budgets;
- commitment to provide secure budget lines to support long-term and effective equipment maintenance systems;
- the expectation that a cold chain equipment maintenance information system will maintain records and facilitate monitoring by managers of key indicators; and
- the requirement that an equipment inventory is available and kept up to date.

In addition to national and subnational maintenance policies, larger health facilities should develop their own equipment maintenance policies. These facility-level policies can further clarify roles and responsibilities, commit funding, reference standard practices, and establish verification and payment procedures for maintenance and repair activities.

¹⁹ Mid-level management course for EPI managers: Module 8. Geneva: WHO, EPI Cold Chain Management; 2004. Available at: http://www.afro.who. int/index.php?option=com_docman&task=doc_download&gid=6567, accessed 15 June 2016.

3.2 Human resources

Equipment maintenance and repair systems depend on many different types of staff, including:

Equipment users: Equipment users may be health care workers, vaccine managers, custodial staff or in-house technical staff. These users must know how to: use equipment correctly, monitor temperatures, identify equipment performance problems, report problems, and perform basic preventive maintenance procedures. Refresher training, job aids and supportive supervision can help reinforce the role of these staff members in maintaining cold chain equipment.

Technicians: Staff members that have training in technical areas such as mechanics, refrigeration and/or electronics. These staff can perform most of the repair procedures for almost all types of cold chain equipment. Examples of potential job descriptions for entry-level and senior maintenance technicians are shown in Annex 4.

Engineers: Staff members that are qualified in a specific branch of engineering, such as electrical, mechanical or electronics engineering, and have advanced academic training. These staff members are able to perform complex repair procedures and help plan, implement and manage equipment maintenance and repair systems.

Managers: Maintenance team managers, immunization programme cold chain managers, immunization service managers and supervisors are essential to running effective maintenance and repair systems. These managers are responsible for planning training activities, updating and distributing SOPs, reviewing equipment temperature records, monitoring maintenance activities and outcomes, and budgeting and controlling the resource requirements of these maintenance systems.

Support staff: Administrative staff, data collectors, data managers, drivers and other support staff will ensure that the right resources and information are available to implement maintenance and repair services.

3.3 Financial resources

Effective maintenance and repair systems require a long-term financial investment to support the planning, training, staffing, equipping and operating of these systems. An effective maintenance and repair system will justify its operating costs as it successfully increases the lifetime and uptime of equipment and supports immunization programme performance by reducing unexpected equipment failures. Financial resources are required to run an effective maintenance and repair system, and these resources must be included in multiyear and annual work plans and budgets. These plans and budgets must include:

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- salaries and wages for technical staff (such as clinical engineers, technicians, craftspeople) as well as support staff (such as secretaries, cleaners, drivers);
- staff training;
- spare parts and consumables;
- tools and testing equipment;
- workshops and offices;
- computers and technical reference materials;
- travel and transportation; and
- office supplies.

3.3.1 Training

Providing technicians and equipment users at all levels of the health system with training on their roles in an effective equipment maintenance and repair system requires planning and budgeting. Capacity-building training can prevent many of the common causes of equipment failure and improve equipment performance.

Training should reinforce key messages during supportive supervision, on-the-job mentoring and technical assistance. The length and content of training courses can vary based on participant background and job requirements²⁰ Training curricula should use examples of national equipment installation, equipment maintenance and vaccine-handling SOPs during training exercises.

3.3.2 Spare parts

One of the common reasons cited for failure to repair equipment is the lack of available spare parts. It is important that maintenance plans and budgets include the purchase and control of spare parts and consumables. Spare parts planning and budgeting will require that maintenance records are available and analysed to help forecast the consumption of spare parts and identify the required content, quantity and timing of spare part orders. Deciding where in the country to keep the physical inventories of spare parts is an important aspect of the plan. In addition to spare parts, it is important that the necessary tools and testing equipment are available. A basic toolkit is available in the cold chain equipment section of the supply catalogue maintained by

²⁰ The cold chain and immunization services: Experiences of the southern nations, nationalities and peoples' regional state. Boston (MA): John Snow, Inc.; 2012. Available at: http://www.jsi.com/JSIInternet/Inc/Common/_ download_pub.cfm?id=13380&lid=3, accessed 15 June 2016.

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UNICEF SD.²¹ Common consumables that must be budgeted for include refrigerant gas, brazing materials, copper pipe and cleaning agents.

3.3.3 Transport and communication

Another common barrier to equipment maintenance and repair is the lack of transportation needed to mobilize technicians to repair broken cold chain equipment. When developing and budgeting for an equipment maintenance and repair system, it is important to provide cold chain technicians with reliable access to shared or dedicated transport options. Transport and funding systems need to be in place in all regions and at all levels of the vaccine supply chain and must support travel and transport costs.²²

Establishing a communication link between vaccine storage points and a maintenance specialist is essential to a maintenance system and can save time and resources. Often, instructions on how to fix minor problems or diagnose the causes of the problems can be given by phone, either resolving the fault or ensuring that the technician travels with the adequate tools and spare parts.

²¹ UNICEF Supply Catalogue. Copenhagen: UNICEF. Available at: www.supply. unicef.dk/catalogue/, accessed 15 June 2016.

²² Cuninghame C, Forster G, Saunders C. Transport management: a selflearning guide for local transport managers of public health services. Arlington (VA): USAID | Deliver Project, Task Order 1; 2010. Available at: http:// deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/TMS_Guide.pdf, accessed 15 June 2016.

Management of an effective maintenance and repair system will require coordination, commitment and leadership from many different partners involved not only with the national immunization programme but also with the overall national health care system.

4.1 Roles and responsibilities

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Identifying how partners will work together begins by understanding the various roles and responsibilities that must be met in order for maintenance and repair systems to operate effectively. Table 1 shows potential partner roles and responsibilities.

Table 1 – Roles and responsibilities

Role	Responsibilities			
Ministry of health and	develop equipment maintenance policies;			
immunization programme	 develop a multiyear equipment maintenance plan and budget; 			
managers	• develop SOP templates for adaptation by facilities and use in training and work duties;			
	 develop policies on donated equipment, such as requiring WHO PQS-prequalified equipment or promoting equipment standardization policies; 			
	 establish an equipment maintenance reporting and supervision system for both immunization and maintenance services staff; 			
	 ensure that financial, material and human resources are available where and when needed for equipment maintenance and repair; 			
	 regulate the relevant departments (EPI, repair, transport) against national equipment maintenance standards; 			
	• establish a coordination team and mechanism that oversees equipment maintenance planning, budgeting and monitoring; and			
	• enforce equipment maintenance policies as an essential part of the health system.			
Maintenance system	• coordinate and plan equipment maintenance and repair activities;			
managers and technicians	• control financial and human resources to deliver equipment maintenance activities;			
	• order and control spare parts and materials to ensure sufficient quality and quantity;			
	• monitor work by government-owned or contracted (outsourced) maintenance teams;			
	• develop, update and distribute SOPs for users and technicians;			
	• train equipment users on operation and routine maintenance of equipment;			
	• ensure suitable cold chain equipment workshop facilities; and			
	• determine cost-effectiveness of maintenance services.			
Health facility management	 follow national legislation, regulations, standards and policies; 			
	 develop facility-level policies and standards; 			
	 ensure routine monitoring of equipment performance; 			
	• report equipment faults immediately to responsible maintenance service providers;			
	 confirm services performed and help ensure proper documentation of maintenance and repair records; 			
	 monitor outcomes of maintenance; and 			
	• educate new users on proper operation and routine equipment maintenance tasks.			
Finance officers	 allocate funds for staff time, transport, spare parts and materials in recurrent maintenance budgets; 			
	 allocate funds for tools and workshop requirements; 			
	 allocate funds for training of users and technicians; and 			
	 develop and pay maintenance contracts promptly and according to clear performance criteria and terms. 			

Role	Responsibilities
Procurement officers	 prepare and review procurement documents in collaboration with maintenance technicians to ensure that:
	- equipment requirements are well documented;
	- standardization policies are considered when selecting new equipment;
	 information on performance of existing equipment is considered when selecting new equipment;
	- technical criteria are weighed alongside economic criteria when making tender awards;
	 spare parts consumption and requirements are incorporated into procurement requests; and
	 outsourced maintenance contracts are awarded to qualified maintenance contractors, and contracts clearly define payment terms and conditions.
Equipment users	 follow SOPs and job aids to perform preventive maintenance;
	 operate equipment properly and safely;
	 monitor equipment temperatures;
	 report equipment faults immediately; and
	• monitor outcomes of maintenance.

EPI = Expanded Programme on Immunization; PQS = performance, quality and safety (WHO); SOP = standard operating procedure; WHO = World Health Organization.

4.2 Training programmes

Managers should ensure that staff have access to practical, hands-on training that demonstrates the skills required to correctly operate, maintain or repair cold chain equipment. SOPs, updated to include important information from equipment-user manuals, can be used as the foundation for training²³

Types of training programmes for users and technicians may include:

- 1. **Basic training:** Develops the fundamental knowledge about operating and basic maintenance of cold chain equipment, including information specific to common models in use.
- On-the-job training: Shows new technicians how to work in health care settings, keep required records, control spare parts and update equipment inventories. It may be provided to new technicians by regional or national technical managers.
- Skill-development training: Provides training on specialized tasks by providing opportunities to observe, followed by practice. May include short-term training courses at technical training institutes.

²³ Care and repair of refrigerators for vaccine storage: Training modules for refrigerator technicians 1985 to 1988. Geneva: WHO; 1988. Available at: http://www.path.org/vaccineresources/files/WHO_CCE_maitenance%20 modules.htm, accessed 15 June 2016. Staff should be trained when starting a new job, when SOPs change, when new equipment is introduced, or when opportunities to improve equipment maintenance and repair systems are identified – for example, after an EVM assessment. For infrequent maintenance procedures, refresher training may also be necessary. Supervisors should be required to identify and support staff who will benefit from on-the-job training or additional skill-development training.

Local technical resource centres can help ministries of health to develop and deliver maintenance training programmes, prepare and update SOPs, and monitor maintenance system performance.²⁴

4.3 Monitoring system performance

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Monitoring the equipment maintenance and repair system at national, regional and health facility levels can help ensure its long-term success, in part by helping justify the budget needed to support the system costs. Regular reporting of maintenance and repair services, field visits by supervisors, number of staff trained, consumption of spare parts and miles travelled are common components of many equipment

²⁴ In India, the National Cold Chain & Vaccine Management Resource Centre (NCCVMRC) supports the ministry of health in developing reference materials and training programmes for cold chain handlers and equipment technicians. More information can be found at: http://www.nccvmtc.org/ About_Us.aspx, accessed 15 June 2016 maintenance monitoring plans. Tracking of equipment performance indicators can also help provide evidence of the benefits and savings gained, thus demonstrating the value of the maintenance and repair system.

The monitoring system should aim to provide relevant information to achieve two different but complementary objectives:

- 1. Assess the progress towards achieving a full implementation of the equipment maintenance plans.
- 2. Evaluate the impact of the equipment maintenance and repair systems on performance indicators.

Monitoring procedures should be standardized and communicated in policies and SOPs.

4.3.1 Performance indicators

Performance indicators help supervisors and managers understand when a programme is working well and where to make improvements. In immunization programmes, the vaccine coverage rate for the third dose of diphtheria, tetanus and pertussis is a familiar performance indicator that is closely monitored locally, nationally and globally to indicate the success of an immunization programme. It may be practical to identify one or two indicators to help the national immunization programme manager or other senior managers track the performance of the maintenance and repair system.

Potential high-level cold chain maintenance and repair system indicators include:

- percentage of cold chain equipment functioning at a specific time point (national or subnational);
- number of repairs performed over a certain time frame per geographical area; and
- number of high-temperature and low-temperature alarms in the last 30, 180 and 360 days.²⁵

In contrast, technical managers and staff responsible for day-to-day implementation of the equipment maintenance and repair plans, and for monitoring budgets, may monitor a larger number of indicators, including, for example, temperatures, spare part consumption, spare part stock levels or the availability of an SOP.

²⁵ High-temperature and low-temperature alarms are documented in the WHO PQS performance specifications for 30-day temperature monitoring devices as follows: 1) low alarm setting – exposure to a single temperature event of -0.5°C or below for 60 minutes; 2) high alarm setting – exposure to a single temperature event of +8°C or above for 10 hours. (See section 4.2.12 in http://www.who.int/immunization_standards/vaccine_quality/ who_pqs_e06_tr06_3.pdf, accessed 15 June 2016).

When identifying a maintenance service model to use to provide equipment maintenance and repair services, recognize that there is unlikely to be a single service model suitable for all facility types, geographical locations, equipment types or maintenance procedures.

A mix of government, parastatal and private maintenance providers may be required in many countries. The primary consideration for selecting an equipment maintenance service model should not be cost but instead the proven ability of service providers to conduct repairs quickly and with a high level of quality, accompanied by accurate and timely service records.

Potential sources for finding skilled technicians include:

- Ministry of health clinical (or biomedical) engineers: These in-house technicians are often employed by the ministry of health to maintain medical equipment requiring calibration, maintenance, repair, user training and decommissioning.
- Parastatal technical organizations: In some countries, partially or fully government-owned or government-funded technical parastatal organizations can be a source of highly specialized cold chain equipment technicians and training programmes. Although these organizations may function like a private company, they are under government oversight.²⁶
- **Private technical companies or individuals:** These private technicians may work in national, regional or local companies or as independent contractors.

 Manufacturer or appointed agent: Some equipment, including centralized temperature monitoring systems or other highly specialized electronic equipment, may need to be repaired by the manufacturer or its appointed repair agent.

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When *outsourcing* maintenance services, do not underestimate the level of effort required to monitor and manage service contractors. Setting clear expectations, ensuring that performance requirements are written into contracts and job descriptions, and making sure that payment terms are met prior to prompt payment is important. Table 2 outlines the potential advantages of government and private maintenance service providers.

When assessing service provider options, consider the list of questions below:

- Is there an existing network of ministry of health equipment repair workshops and are spare parts, tools and testing equipment readily available in all regions?
- Are there technicians or engineers in other health programmes or at larger health facilities that can be accessed?
- Are there training institutions and nongovernmental organizations that can support user and technician capacity-building?
- Are there skills within the private sector that can be accessed?

Table 2 – Advantages of public and private maintenance service providers

Government-employed technicians	Privately employed technicians
 integration of communication to/from health centres within the health system; 	• services are not limited by the availability of government staff;
• potential for more control over service providers;	 specialized skills can be hired only when needed;
 no dependence on a single contracted provider; and potential to integrate cold chain equipment 	 may reduce capital and staffing investments needed by government;
maintenance with larger public health care technology and infrastructure maintenance systems.	 can be used where there is limited availability of government technicians; and
	• payment restricted to terms of contract deliverables.

²⁶ Examples of parastatal technical organizations are India's National Cold Chain & Vaccine Management Resource Centre and National Cold Chain Training Centre. These organizations train cold chain technicians and provide repair, monitoring, calibration, procurement and planning support. More information can be found at: http://www.technet-21.org/images/ TC2015/06_Country_Innovations_India_Srihari_Dutta.pdf and http://www. nccvmtc.org/default.aspx, accessed 15 June 2016.

- Are manufacturers' representatives and preferred suppliers accessible locally?
- Which maintenance organizations, government agencies and private companies have a proven, positive track record?

Regardless of the service provider, it is essential to establish an institutional or contractual framework with clearly defined maintenance standards, maintenance intervals and maximum acceptable emergency response times to protect vaccines from damage or loss.²⁷ For all maintenance service models, the development of contracts with clearly defined tasks, schedules, validation mechanisms and payment terms is essential. Section 5.1 below discusses contractual requirements.

5.1 Contract management

When deciding to contract external maintenance service providers, there are three major types of maintenance service contracts to consider: work package contracts, performance-based contracts or lease contracts.²⁸ These contracts are described as follows:

Work package contracts: The work package contract is the most basic type of maintenance contract. The equipment owner, either the health facility or ministry of health, will plan and control all maintenance activities and strategies and then determine what, when and who will perform the required maintenance activities.

Performance-based contracts: In performance-based maintenance contracts, the maintenance service provider will guarantee a certain level of system performance, such as number of repairs, preventive maintenance schedule compliance, uptime percentage,²⁹ or mean time to repair³⁰ to the customer. The service provider is typically paid a flat rate for meeting these performance standards and manages the resources and activities involved. Data tracking systems are necessary for governments to verify service provider compliance with agreed performance standards.

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- ²⁷ Temple-Bird C, Kaur M, Lenel A, Kawohl W. 'How to Manage' Series for Healthcare Technology. Guide 1: How to Organize a System of Healthcare Technology Management. Lewes: Ziken International Consultants Ltd; 2005. Available at: http://www.who.int/management/organize_system_%20 healthcare.pdf, accessed 15 June 2016.
- ²⁸ Martin HH. Contracting out maintenance and a plan for future research. Journal of Quality in Maintenance Engineering. 1997;3(2):81–90.
- ²⁹ Uptime percentage = uptime minutes ÷ planned runtime minutes × 100.
- ³⁰ The mean time to repair represents the average time required to repair a failed component or device. As equipment reliability improves, the mean time to repair should trend downward as the failures become less severe. More information can be found at: http://en.wikipedia.org/wiki/Mean_ time_to_repair, accessed 15 June 2016.

Lease contracts: A lease contract allows the ministry of health to use equipment without owning it. Use of the equipment is charged at a monthly, quarterly or yearly rate. It eliminates the need for the ministry of health to commit capital and shifts the burden of maintenance to the lessor, that is, to the entity that owns the equipment.

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As part of contracting with the ministry of health, a private service provider should be required to complete a registration process, which ensures that a company has a workshop, technical staff with appropriate skills, transport, materials and financial systems in place. It is important that the registration results are reported back to the immunization service delivery point or vaccine store where the equipment is installed, and that these sites register the person/company as a supplier of maintenance services.³¹

All contracts will need to include the following information:

- period of agreement;
- ownership and location of spare parts;
- preventive maintenance schedule;
- service response rate;
- sanctions in case of noncompliance;
- payment terms.

Identification and implementation of maintenance service models should be systematic and transparent.

5.2 Equipment warranties and after-sales service

When procuring or purchasing cold chain equipment from UNICEF SD, there are long-term arrangement (LTA) agreements between UNICEF SD and equipment suppliers that stipulate the warranty conditions for cold chain products. Typically, the warranty period for cold chain equipment is one year, during which the supplier must repair goods if defects appear after delivery. The supplier warrants to UNICEF, among other things, that:

- the goods shall be new and factory packed and shall conform to the LTA documents;
- the goods are free from defects in workmanship and materials;
- the goods are contained or packaged in a manner adequate to protect them; and

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³¹ More information on the importance of registering maintenance service providers can be found in the 'How to Manage' Series for Healthcare Technology, including Guide 1, section 4.1 (How to Organize a System of Healthcare Technology Management) and Guide 5, section 3.5 (How to Organize the Maintenance of Your Healthcare Technology). Available at: http://www.who.int/management/resources/equipment/en/index1.html, accessed 15 June 2016.

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• it has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources necessary to perform its obligations under the LTA.

The warranty period commences after UNICEF's acceptance of a delivery made by the supplier or its authorized representative[s] and terminates 12 months after delivery, or within any such longer period of time as contracted for most vaccine refrigerators or ice-pack freezers. The warranty period for cold rooms and freezer rooms is usually two years but may vary depending on the manufacturer. When ministries of health purchase equipment directly from the manufacturer rather than from UNICEF, it is important to include similar terms in tender agreements.

Performed by a manufacturer or local supplier, aftersales service can be periodic or as required to maintain equipment either during or after a warranty period. Aftersales service can help manufacturers and suppliers build positive, long-term relationships with their customers, including public-sector clients such as immunization programmes. Many refrigerator companies already offer limited after-sales service, and additional provisions may be included in purchase arrangements. When procuring new cold chain equipment, it can be valuable to include after-sales service terms as a way of securing a subset of the required maintenance and repair services.

An effective cold chain equipment and maintenance system will be supported with a national cold chain equipment maintenance and repair plan and budget. Annex 5 shows a proposed outline of a national maintenance plan and guidelines that may be useful to countries interested in drafting such a plan.

The WHO EVM assessment criteria include verifying that the maintenance of buildings, cold chain equipment and vehicles is satisfactory. Assessors will be looking for evidence that a cold chain preventive maintenance programme is established and implemented. A national or facility-based cold chain maintenance and repair plan and budget should be available that demonstrates that a cold chain equipment maintenance and repair system is in effect. Indicators of an equipment maintenance and repair system include:

- a written planned preventive maintenance programme;
- a preventive maintenance checklist for refrigeration equipment;
- evidence that the preventive maintenance programme is being followed, such as the presence of written SOPs at all vaccine storage points, updated maintenance service job cards and an accurate equipment inventory;
- evidence that cold rooms/refrigerators/freezers have recently been cleaned and defrosted;
- someone is assigned to carry out routine maintenance;
- when solar refrigerators are used, solar panels are clean and completely unshaded by buildings, trees and overhead cables; and
- when battery-powered solar refrigerators are used, there is evidence that the battery electrolyte has been checked recently.

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Resources

• WHO Effective Vaccine Management standard operating procedures (SOPs). Geneva: WHO; 2012. Available in English and French. All SOPs must be downloaded as a ZIP file from: http://www.who.int/immunization/programmes_ systems/supply_chain/evm/en/index2.html

Individual SOP templates can then be opened and modified, including the following SOPs:

- EVM-SOP-E5-02: Looking after cold rooms and freezer rooms
- EVM-SOP-E5-03: Installing and looking after vaccine refrigerators and freezers
- EVM-SOP-E5-04: Looking after standby generators
- EVM-SOP-E5-05: Looking after voltage regulators
- EVM-SOP-E7-05: Loading and operating refrigerated vehicles.
- 'How to Manage' Series for Healthcare Technology is available at: http://www.who.int/management/resources/ equipment/en/index1.html.
 - Guide 1: How to Organize a System of Healthcare Technology Management
 - Guide 2: How to Plan and Budget for Your Healthcare Technology
 - Guide 3: How to Procure and Commission Your Healthcare Technology
 - Guide 4: How to Operate your Healthcare Technology Effectively and Safely
 - Guide 5: How to Organize the Maintenance of Your Healthcare Technology

- Guide 6: How to Manage the Finances of Your Healthcare Technology.

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These materials are also available as a 15-hour OpenLearnWorks course on health care technology management at: http://www.open.edu/openlearnworks/ mod/oucontent/view.php?id=13237.

 The WHO Medical Devices Technical Series consists of reference documents to assist countries in ensuring improved access to, and quality and use of, medical devices. Available at: http://www.who.int/medical_devices/ management_use/en/.

The following three modules in this series are available in English, French and Spanish:

- Introduction to Medical Equipment Inventory Management WHO Medical Devices Technical Series;
- Medical Equipment Maintenance Programme Overview; and
- Computerized Maintenance Management System.
- WHO Biomedical engineering global resources website. Available at: http://www.who.int/medical_devices/support/en/.
 WHO recognizes that trained and qualified biomedical engineering professionals are required to design, evaluate, regulate, maintain and manage medical devices as well as provide training on their safe use in health systems around the world. This website provides access to the Global Biomedical Engineering Education and Professional Database, identifying biomedical/clinical engineering teaching units and associations worldwide.

Annex 1. Template for a preventive maintenance job aid

1. Check installation

Refrigerator:

- is out of direct sunlight;
- is in a well-ventilated area:
- is clear of any heat source;
- is on a level floor:
- has enough space for air circulation; i.e. there is more than:
 - 50 mm between the back and the wall.
 - 100 mm between the side of the refrigerator with the grille and the wall: and
 - 200 mm between vaccine refrigerators.

3. Store vaccines properly

The vaccine compartment includes:

- an alcohol stem thermometer or an electronic temperature monitor and an electronic freeze indicator in the coldest area:
- no food or drink:
- vaccines stored so that those with earliest expiration date are easiest to access; and
- notice of emergency plan for vaccine storage if equipment fails or there is a power cut.

5. Important refrigerator care



Daily tasks

- 1. check and record temperature within the refrigerator each morning and evening; and
- 2. if the temperature is greater than +8°C or less than +2°C. take action.



Weekly tasks

- 1. remove any water at the bottom of the refrigerator with a cloth or by draining through the drainage hole;
- 2. wipe off water droplets from the inside wall: and
- 3. check if the lid gasket is sealing when the lid is closed.

2. Protect the power supply

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Refrigerator power supply is protected with:

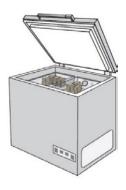
- a "Do Not Unplug" sign by the outlet:
- a "Do Not Interrupt Power" warning label by the circuit breaker;
- signs including current emergency contact information and notification of emergency plan; and
- a voltage regulator.



4. Arrange packaged vaccines

Vaccine cartons and vials are:

- stored in baskets or in uncovered containers with slotted sides placed inside these baskets;
- stored with vertical space between stacks of cartons to allow air to circulate:
- not in contact with the walls of the refrigerator or freezer;
- not stored directly in front of a fan or outlet from the freezer compartment.





Monthly tasks

- 1. clean the refrigerator with lukewarm water and mild detergent; and
- 2. clean the grill on the side of the refrigerator.

6. How to defrost a vaccine refrigerator

- 1. Transfer vaccines to a working refrigerator or cold box with conditioned ice-packs.
- 2. Turn off the power supply to the refrigerator.
- 3. Leave the lid or door open and wait for the ice to melt. Do not try to remove the ice with a knife or other sharp object as doing this can permanently damage the lining.
- 4. Once the ice has melted, clean and dry the inside of the appliance.
- 5. Turn on the power supply to the refrigerator again.

When the temperature falls to less than or equal to +8°C or lower (but not less than +2°C), return the vaccines, diluents, and/or cool water-packs or water bottles.



••••• Annex 2. Maintenance checklist for solar refrigerators and freezers³²

Maintenance tasks (daily)

Responsible staff person name: ____

Task	Check
Check thermometer on refrigerator for acceptable temperature (+2°C to +8°C).	
Record refrigerator temperature on daily temperature record (twice daily).	
Check other indicators for correct operation (for example, 30-day temperature recorder for alarms, light- emitting diodes (LEDs) on refrigerator for correct daytime operation, battery voltmeters).	
Ensure efficient operation: • open only when needed and close as soon as possible	
• do not store personal food or drinks	
 load vaccine and ice-packs according to manufacturer's recommendations. 	
Check that refrigerator lid(s) fit tightly and are in position.	
If freezer is not completely frozen in the morning, wipe away interior moisture.	
Check that ventilation of refrigerator is not blocked.	
Report to supervisor any problems that cannot be solved.	

Maintenance tasks (monthly)

Responsible staff person name: __

Task	Check
Disconnect power.	
Drain or wipe up refrigerator condensate.	
Clean appliance inside, door seals, ventilation grills, condenser and outside.	
Defrost as necessary (may be more frequent than monthly).	
Check tightness of door seal.	
Clean solar array.	
Check solar array for shading from plants; trim plants that shade solar array.	
Check solar array for other shading (e.g. new construction); report any findings to supervisor.	
Check wiring for signs of damage (animals, storm, or accidents); report any findings to supervisor.	
Reconnect power.	
Check for expected operation (e.g. indicator lights, fans operating, cooling as expected).	
For flooded-battery systems: observe electrolyte level through the clear casing and report to supervisor if electrolyte is below level indicator.	

³² WHO, UNICEF. Introducing solar-powered vaccine refrigerator and freezer systems: A guide for managers in national immunization programmes. Annex H. Geneva: WHO; 2015. Available at: http://www.who.int/ immunization/documents/9789241509862/en/, accessed 15 June 2016.

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Maintenance tasks (biannually)

Responsible technician name:

Task	Check
Oil hinges (may need to be more frequent in some locations).	
Tighten all electrical connections.	
Tighten all mechanical connections.	
For flooded-battery systems, service batteries (i.e. record specific gravity of each cell, clean terminals, inspect condition of plates, add distilled water as required, apply equalizing charge as needed and check battery enclosure ventilation).	

•••• Annex 3. Contingency plan template

Prepared on:	
•	
Name of facility:	
,	

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When to act:

- 1. Power failure for more than 18 hours.
- 2. Major repair needed.
- 3. <other>

Who will act (name and designation):

What to do in event of extended power failure:

- 1. monitor temperatures; if vaccine storage compartment reaches +8°C, go to Step 2;
- 2. shift the vaccines to cold boxes with conditioned frozen water-packs;
- 3. move vaccines to health centre <health centre name> and store in the ice-lined refrigerator; and
- 4. contact <name> if there are unexpected cold chain capacity issues to identify alternative storage location.

What to do in case of equipment failure:

Vaccine refrigerator

- 1. shift the vaccines to cold boxes with conditioned frozen water-packs;
- 2. contact <name> to register repair service request and ask for projected service date;
- 3. transfer vaccines to health centre <health centre name> if repair delay is greater than 24 hours; and
- 4. if repair service is not completed within 7 days, contact <name>.

Ice-pack freezer

- 1. use locally available domestic freezer;
- 2. use commercial ice source;
- 3. access frozen water-packs from a nearby health facility;
- 4. contact <name> to submit a repair request and identify a projected service date; and
- 5. if repair service is not completed within 7 days, contact <name>.

Voltage stabilizer

- 1. store vaccines in cold box with conditioned frozen water-packs; and
- 2. disconnect voltage stabilizer and contact <name> to order replacement immediately.

Annex 4. Entry-level and senior technician job descriptions

Entry-level/mid-level technician job description

Performs tasks involving the installation, maintenance and decommissioning of cold chain equipment.

These activities may include:

- perform repair and technical maintenance procedures for cold chain equipment according to established standard operating procedures (SOPs);
- document maintenance and repair services performed according to established SOPs, including tracking spare parts used;
- assist Expanded Programme on Immunization (EPI) logistics team to manage data for cold chain equipment, including temperature records, maintenance records, spare parts inventory and data for the national inventory of cold chain equipment;
- train users on proper operation, monitoring, and care of cold chain equipment;
- support installation of new cold chain equipment as required;
- support identification and decommissioning of obsolete cold chain equipment; and
- perform other duties as required.

Education/experience: At least one year of vocational training in the electrical, mechanical, and/or refrigeration field. Demonstrated computer skills on Microsoft Excel and Word. Good communication, presentation and organizational skills. [For mid-level technician: At least two years of experience as a cold chain equipment or medical equipment technician, preferably in a health care setting.]

Senior/manager technician job description

Performs tasks involving the installation, maintenance and decommissioning of cold chain equipment.

These activities may include:

- perform and advise on a wide variety of routine, complex and specialized tasks associated with the installation, maintenance and repair of equipment;
- document maintenance and repair services performed according to established SOPs, including tracking spare parts used;
- assist EPI logistics team to manage data for cold chain equipment, including temperature records, maintenance records, spare parts inventory and data for the national inventory of cold chain equipment;
- train and mentor entry-level and mid-level technicians and ensure that appropriate SOPs and job aids are available;
- train users on proper operation, monitoring and care of cold chain equipment;
- manage inventory of required spare parts for ongoing maintenance and repair of cold chain equipment;
- coordinate transport for cold chain technicians and/or equipment to facilitate needed maintenance and repairs;
- coordinate and/or supervise maintenance and repair services performed by external service providers;
- assist in developing technical specifications for new equipment purchases;
- support installation of new cold chain equipment as required;
- support identification and decommissioning of obsolete cold chain equipment;
- provide input when EPI cold chain equipment policies and procedures are updated; and
- perform other duties as required.

Education/experience: At least two years of vocational training in electrical, mechanical and/or refrigeration technologies. A minimum of five years of experience, preferably in a health care setting, with management or supervisory responsibilities.

•••• Annex 5. Example outline for national cold chain maintenance plan and guidelines

1.0 Mission and vision

2.0 Situational analysis

- 2.1 National immunization programme
- 2.2 Cold chain system structure
- 2.3 Maintenance policy
- 2.4 Stakeholders and actors in the national maintenance system
- 2.5 Service provider landscape (public, parastatal and private)
- 2.6 Strengths and weakness of current system

3.0 National maintenance and repair guidelines

- 3.1 High-level description of cold chain equipment maintenance system
- 3.2 Roles and responsibilities
- 3.3 Routine preventive maintenance procedures
- 3.4 Repair procedures
- 3.5 Installation and decommissioning procedures
- 3.6 Workshops, spare parts and tools
- 3.7 Record-keeping and data management (includes inventory)
- 3.8 Monitoring and supportive supervision
- 3.9 Budget

4.0 Improvement plan

- 4.1 Strengthening human resources
- 4.2 Ensuring availability of adequate financial resources
- 4.3 Facilitating system operations (spare parts, transport and information systems)
- 4.4 Monitoring for continuous improvement
- 4.5 Budget for improvement plan

Annexes

- A. Maintenance and repair standard operating procedures
- B. Maintenance and repair job aids

Notes		









