FINAL
DRAFT

INTERNATIONAL
STANDARD

**ISO/FDIS
5477**

ISO/TC **215**

Secretariat: **ANSI**

Voting begins on:
2023-09-15

Voting terminates on:
2023-11-10

Health informatics — Interoperability of public health emergency preparedness and response information systems

Reference number
ISO/FDIS 5477:2023(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The public health emergency preparedness and response operations are the critical component of the Global Health Security as well as the national multi-jurisdictional and multi-sectoral emergency response. All these operations rely on a unity of command approach, which FEMA defines as principles clarifying the reporting relationships and eliminating the confusion caused by multiple, conflicting directives. Another critical component of emergency response operations is implementing disaster management interoperability that supports the unity of command through equipping all responders with a clear understanding of their own responsibilities and functional interdependencies with other responders. From an information management perspective, it is important to note that the disaster management interoperability processes include development of communication channels that allow to share information via voice, data signals and electronic data developed on standardized terminology and vocabulary.

This document has been developed in response to the worldwide demand for strengthening PH EPR information systems, ensuring better preparedness at national and international levels, emerging pathogens, including COVID-19, chemical and nuclear accidents, environmental disasters and introduction of the threat of criminal acts and bioterrorism.

The document has been developed based on concepts and methodology described in:

— 2015 WHO Framework for a Public Health Emergency Operations Centre and supporting WHO Handbooks A and C[33];

— ISO/IEC 25012[34];

— ISO 30401[35];

— ISO 13054[36];

— ISO 22300[37];

— ISO 22320[19];

— ISO 1087[38].

Health informatics — Interoperability of public health emergency preparedness and response information systems

1 Scope

This document provides business rules for PH EPR information systems. It includes a description of the EPR information systems domain. It also includes an informative framework for mapping existing semantic interoperability standards for emergency preparedness and response to PH EPR information systems.

The primary target audience for this document is policy makers (governmental or organizational), regulators, project planners and management of PH EPR information systems, PH EPR data analysts and informaticians. The contents is also of interest to other stakeholders such as incident managers, PH educators, standards developers and academia.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1.1
all-hazards approach
integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters, including internal emergencies and a man-made emergency (or both) or natural disaster

Note 1 to entry: The all-hazard approach acknowledges that, while hazards vary in source (natural, technological, societal), they often challenge health systems in similar ways. Risk reduction, emergency preparedness, response actions and community recovery activities are usually implemented along the same model, regardless of the cause.

3.1.2
case definition
<public health preparedness and surveillance> set of standard criteria for classifying whether a person has a particular disease, syndrome, or other health condition

Note 1 to entry: Use of an agreed-upon standard case definition ensures that every case is equivalent, regardless of when or where it occurred, or who identified it. Furthermore, the number of cases or rate of disease identified in one time or place can be compared with the number or rate from another time or place.

3.1.3
code set
<data> collections of codes or identifiers that are used to represent specific values within a value set

Note 1 to entry: These codes are often standardized and internationally recognized, such as ICD-10 codes for diseases or SNOMED CT codes for clinical terms.

3.1.4
common operating picture
COP
unified and shared understanding of a situation or scenario, that involves gathering and integrating data, information, and intelligence from various sources and presenting it in a comprehensive and accessible manner

Note 1 to entry: The COP aims to provide all stakeholders with a real-time, accurate, and synchronized view of the operational environment, enabling effective decision-making, coordination, and communication among the involved parties.

3.1.5
concept
<public health emergency preparedness and response data vocabulary > set of terms or concepts that have been agreed upon and adopted by a broader community or standard-setting organization in the context of public health emergency preparedness and response

Note 1 to entry: Public health emergency preparedness and response concepts are codified within the public health emergency preparedness and response data *vocabulary* (3.1.26). They designed in a way to ensure that data is collected and reported in a standardized and consistent manner, enabling effective communication and decision-making during emergency response.

3.1.6
critical information requirement
CIR
high-priority subset of *EEIs* (3.1.11) that triggers immediate or mandatory action

Note 1 to entry: These are elements of information specifically requested by incident leaders. These items are of such importance that leaders are notified immediately when the Planning Section receives updates on a CIR item.

3.1.7
data governance
process of overall management of the availability, usability, integrity, and security of the data employed in an enterprise assuring that the decision-making process prioritizes investments, allocates resources, and measures results

Note 1 to entry: Data governance is a component of the *information governance* (3.1.13).

3.1.8
disaster management interoperability
ability of systems, personnel, and equipment to provide and receive functionality, data, information and/or services to and from other systems, personnel, and equipment, between both public and private agencies, departments, and other organizations, in a manner enabling them to operate effectively together

Note 1 to entry: It allows emergency management/response personnel and their affiliated organizations to communicate within and across agencies and jurisdictions via voice, data, or video-on-demand, in real time, when needed, and when authorized.

3.1.9
domain
<information system> logical grouping of data pertaining to a common purpose, object, or concept

Note 1 to entry: The domain defines the context, requirements, and objectives that shape the design, functionality, and capabilities of the information system.

3.1.10
emergency operations centre
EOC
physical location at which the coordination of information and resources to support incident management (on-scene operations) activities normally takes place

Note 1 to entry: An EOC can be a temporary facility or located in a more central or permanently established facility, perhaps at a higher level of organization within a jurisdiction.

Note 2 to entry: EOCs can be organized by major functional disciplines (e.g., fire, law enforcement, medical services), by jurisdiction (e.g., Federal, State, regional, tribal, city, county), or by some combination thereof.

3.1.11
essential elements of information
EEIs
<emergency preparedness> crucial pieces of information necessary for effective planning, response, and coordination in the field of public health emergency preparedness and response

Note 1 to entry: EEIs encompass key data, indicators, and intelligence that are essential for public health agencies and organizations to assess, monitor, and respond to public health emergencies and disasters.

Note 2 to entry: EEIs are specifically tailored to the unique needs and requirements of public health preparedness, including vital information related to disease surveillance, epidemiological data, healthcare system capacity, medical resources availability, population demographics, risk assessments, and other factors influencing public health response efforts.

3.1.12
incident management system
IMS
comprehensive, interoperable organizational model for government, nongovernmental organizations, and the private sector to prevent, protect against, mitigate, respond to, and recover from incidents

Note 1 to entry: It provides stakeholders with a platform for sharing resources, coordinating and managing incidents, and communicating information through shared vocabulary, systems, and processes to successfully deliver the capabilities.

3.1.13
information governance
overall strategy that outlines the responsibility for ensuring appropriate behaviour when valuing, creating, storing, using, archiving, and deleting information for an enterprise

Note 1 to entry: It is a fundamental component of enterprise governance that includes processes, roles, policies, standards and metrics that help an organization achieve its goals.

3.1.14
information system
one or more computer systems and communication systems together with associated organizational resources such as human, technical, and financial resources that provide and distribute information

[SOURCE: ISO/IEC 25012:2008, 4.11]

3.1.15
interoperability
<IT> ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information

Note 1 to entry: IT interoperability is a component of disaster management interoperability.

Note 2 to entry: IT interoperability ensures that diverse technologies can understand, interpret, and utilize information exchanged between them without loss or distortion, allowing the smooth transfer of data, commands, and functionalities between different systems, enabling them to work together in a cohesive manner.

3.1.16
preparedness
<public health> ability to effectively anticipate, respond to, and recover from the impacts of likely, imminent, or current hazard events or conditions

Note 1 to entry: Public health preparedness encompasses the planning, organization, and coordination of resources and actions that is carried out within the context of disaster risk management and aims to build the capacities needed to efficiently manage all types of emergencies and achieve orderly transitions from response through to sustained recovery.

Note 2 to entry: Public health preparedness is based on a sound analysis of disaster risks and good linkages with early warning systems, and includes such activities as contingency planning, stockpiling of equipment and supplies, the development of arrangements for coordination, evacuation and public information, and associated training and field exercises. These must be supported by formal institutional, legal and budgetary capacities.

3.1.17
population health
science of protecting and improving the health of people and their communities through promoting healthy lifestyles, researching disease and injury prevention, and detecting, preventing and responding to infectious diseases and other health threats

Note 1 to entry: The field of population health includes health outcomes, patterns of health determinants, and policies and interventions that link these two.

Note 2 to entry: Population health is a multidisciplinary approach that is based on a variety of disciplines, including epidemiology, biostatistics, social and behavioural sciences, emergency preparedness and response, health policy and management. It is focused on understanding and addressing the health needs of populations, with the goal of improving health outcomes and reducing health disparities.

3.1.18
public health
science and practice of protecting and improving the health of individuals, communities, and populations through the prevention of disease, injury, and other health-related issues

Note 1 to entry: Public health works to promote healthy behaviours and environments, identify and respond to health threats, and address health inequalities and disparities.

Note 2 to entry: Public health is a multidisciplinary field that draws on a variety of scientific and social science disciplines, including epidemiology, biostatistics, environmental health, social and behavioural sciences, and health policy and management. Public health professionals work in a range of settings, including public health departments, healthcare organizations, community-based organizations, academia, and government agencies.

3.1.19
public health and medical situational awareness
knowledge state that results from the process of active information gathering with appropriate analysis, integration, interpretation, validation and sharing of information related to health threats and the health of the human population, as well as health system and human services resources, health-related response assets, and other information that can impact the public's health to inform decision making and resource allocation

Note 1 to entry: Public health medical and situational awareness is critical in emergency response because it enables healthcare professionals to make informed decisions and take appropriate actions to mitigate the impact of the crisis. It allows them to identify potential risks and challenges, assess the capacity of the healthcare system, and develop effective strategies to manage the crisis.

Note 2 to entry: The public health medical and situational awareness plays a significant role in preventing public health emergencies and medical crises by enabling proactive risk assessment and mitigation. It involves identifying potential threats, developing early warning systems, and implementing appropriate preventive measures to prevent or mitigate a crisis.

3.1.20
public health emergency preparedness and response informatics
PH EPR informatics
interdisciplinary science, incorporating knowledge and techniques from multiple fields of research and practice, including epidemiology and surveillance, gathering and distributing information for situational awareness, IT technology and infrastructure development, incident management, and several other disciplines

Note 1 to entry: PH EPR informatics involves the strategic use of informatics tools, methods, and technologies to collect, analyse, exchange, and disseminate critical information and support decision-making processes during emergency situations.

Note 2 to entry: PH EPR informatics enhances the efficiency, accuracy, and effectiveness of emergency response efforts, enabling timely and informed decision-making, resource allocation, and coordination.

3.1.21
public health emergency preparedness and response information system
people, processes and technology involved in planning, acquiring, processing, managing and distributing PH EPR data and information in a coordinated manner, within and across organizational, regional, national and international boundaries to inform EPR decision making, resource allocation, community response and other actions necessary for PH EPR operations.

3.1.22
reference information model
single information model that covers the data domain of activity being addressed by a standards developing organization using this methodology

[SOURCE: ISO/TS 27790:2009, 3.62]

3.1.23
reference standard
single information model that covers the data domain of activity being addressed by a standards developing organization using this methodology

3.1.24
terminology
<public health emergency preparedness and response> specialized language used to describe the concepts, principles, and practices related to medical diseases and conditions, medical procedures and treatments, promoting and protecting populations' health, and preventing, responding and mitigating disasters

Note 1 to entry: Terminology is used to describe code sets, classifications, and vocabulary as a continuum.

Note 2 to entry: Public health terminology includes epidemiology (the study of the distribution and determinants of health and disease in populations), surveillance (the ongoing collection, analysis, and interpretation of health data), health promotion (activities aimed at improving health and preventing disease), and community health (the health status and needs of specific populations or communities).

3.1.25
value sets
<public health and public health preparedness> standardized codes and terms used to represent public health and public health concepts and their associated attributes, such as medical diseases and conditions, medical procedures and treatments, qualitative indicators for evaluation of health protection of populations, and disaster prevention, response and mitigation

Note 1 to entry: Value sets are commonly used in electronic information flows to enable exchanging public health, public health reporting and situational awareness information between all entities involved in public health emergency response.

Note 2 to entry: Standardized value sets are typically created and maintained by standard international public health organizations (i.e., WHO- International Classification of Diseases, ICD), standard development organizations (SDOs), i.e., IHTSDO (SNOMED CT codes), HL7, Regenstrief Institute (LOINC), which are widely adopted in public health.

3.1.26
vocabulary
<public health emergency preparedness and response data vocabulary> precise and standardized language and terminology for the public health emergency preparedness and response electronic data exchange to describe and respond to emergencies, disasters, and public health crises

Note 1 to entry: Public health emergency preparedness and response data vocabulary facilitates precise communication by minimizing or eliminating ambiguity (e.g., SNOMED CT, ICD-11).

Note 2 to entry: Public health emergency preparedness and response vocabulary includes terms related to emergency management, incident management, personal protective equipment, triage, mass casualty incidents, decontamination, and other concepts related to responding to emergencies and disasters that threaten public health.

Note 3 to entry: public health and public health preparedness data vocabulary very often use standardized *value sets* (3.1.25). For example, disability could be described by precise and standardized language, and it could be measured using such value sets as Disability status (a patient describes his/her own disability status), Disability type that described by a clinician (i.e., neurological disability, physical disability).

3.2 Abbreviated terms

CDC	Centres for Disease Control and Prevention
CIR	Critical Information Requirements
COVID-19	Coronavirus Disease 2019
DIS	Draft International Standard
EEI	Essential Elements Information
EOC	Emergency Operations Centre
EPR	Emergency Preparedness and Response
FEMA	Federal Emergency Management Agency
GIS	Geographic Information System
HHS	Department of Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level Seven
IDSR	Integrated Diseases Surveillance and Response
IEC	International Electrotechnical Commission, see ISO/IEC
IHR	International Health Regulations
IMS	Incident Management System
ISO	International Organization for Standardization
ISO/IEC	International Organization for Standardization/ International Electrotechnical Commission
IT	Information Technology
LOINC	Logical Observation Identifiers Names and Codes
PH	Public Health
PHE	Public Health Emergency (see ASPR)

PH EOC-NET	Public Health Emergency Operations Centre Network
PH EPR	Public Health Emergency Preparedness and Response
PHIN VADS	Public Health Information Network Vocabulary Access and Distribution System
SA	Situational Awareness
SNOMED-CT	Systemized Nomenclature of Medicine – Clinical Terms
SOP	Standard Operating Procedure
TC	Technical Committee
URL	Uniform Resource Locator
US	United States
VADS	See PHIN VADS
WHO	World Health Organization
WTO	World Trade Organization

4 Requirements for PH EPR information systems

4.1 Defining the PH EPR information system's domain

Information is the most critical asset during all phases of PH emergencies. It drives a decision-making process that enables situation assessment, risk analysis, resource allocation, response planning, public communication, and monitoring and evaluation.

The PH EPR information systems domain that manages PH EPR information encompasses people, processes and technology, and involves planning, acquiring, processing, managing and distributing PH EPR data and information in a coordinated manner, within and across organizational, regional, national and international boundaries to inform PH EPR decision making, resource allocation, community response and other actions necessary for PH EPR operations.

The PH EPR information systems domain typically includes the data management for the following data domains:

— Emergency preparedness: This domain encompasses data related to planning, training, and resource management in preparation for public health emergencies. It addresses information needs for developing response plans, conducting drills and exercises, establishing communication networks, and ensuring the availability of necessary resources and infrastructure.

— Surveillance and monitoring: This domain includes data to detect and track public health emergencies, such as data from surveillance systems for disease outbreaks, environmental monitoring, syndromic surveillance, and early warning systems. The domain also includes monitoring indicators such as case counts, hospitalizations, deaths, and other relevant data to inform decision-making.

— Risk assessment and modeling: This domain contains data for the evaluation and modeling of risks associated with public health emergencies, such as assessing the potential impact of emergencies, identifying vulnerable populations, estimating the spread of diseases, and predicting resource needs for response efforts. Risk assessment and modeling inform preparedness plans and resource allocation strategies.

— Communication and alerting: This data domain focuses on communication and information dissemination during emergencies, such as data for issuing alerts, warnings, and notifications to relevant stakeholders. Also, it includes data related to the development of communication channels, public messaging strategies, and the coordination of communication efforts across various entities involved in the response.

— Resource management: It focuses on data for the management of resources required for effective response during public health emergencies, tracking and inventorying medical supplies, vaccines, equipment, personnel, and other critical resources. Based on identified needs, this analysis ensures the availability, distribution, and utilization of resources.

— Incident reporting and documentation: This domain encompasses data from the documentation and reporting of incidents, response activities, and outcomes. It includes capturing and storing data on cases, interventions, epidemiological investigations, and outcomes. Incident reporting and documentation systems facilitate retrospective analysis, evaluation, and reporting to stakeholders, regulatory bodies, and the public.

— Collaboration and coordination: It focuses on data demonstrating the facilitation of collaboration and coordination among various stakeholders involved in PH EPR. Also, it contains indicators of coordinating efforts across different agencies, organizations, and jurisdictions to ensure a cohesive and synchronized response.

The PH EPR information systems play a critical role in fulfilling of the following major PH emergency response functions[31]:

— plans and procedures;

— physical infrastructure;

— information and communication technology (ICT) infrastructure;

— information systems and standards;

— human resources.

4.2 General principles of management and conformance

4.2.1 Conformance with general incident management principles

4.2.1.1 General requirements

The PH EPR information systems shall conform with general principles of incident management systems.

4.2.1.2 Utilization of common terminology, PH EPR vocabulary and concepts.

Incident management systems develop and utilize common EPR terminology that allows different organizations to fulfil assigned incident management functions, enhance IT interoperability and minimize confusion.

4.2.1.3 Modular organization

The incident management systems consist of building blocks that can be put in place as needed based on critical incident characteristics. These blocks include information on the incident's size, complexity and a type of hazards that caused the incident.

4.2.1.4 Managing by objectives

The incident commander establishes incident objectives that direct incident management operations. Managing by objectives require:

— Making specific, measurable objectives

— Developing executable strategies, tactics, tasks, and activities to fulfil the objectives

— Benchmarking, evaluating and documenting performance against objectives facilitate the initiation of corrective actions, and inform development of objectives for the next operational period.

4.2.1.5 Incident action planning

Development of coordinated incident action planning guides is crucial. Incident action plans (IAPs) outline incident objectives, tactics, and assignments for operational and support activities.

4.2.1.6 Manageable span of control

Span of control pertains to the number of individuals or resources that one supervisor can manage effectively during an emergency response. Effective spans of control enable supervisors to direct, communicate with and supervise subordinates. Incident management optimal control span is one supervisor to five subordinates. However, the 1:5 ratio is only a guideline. Effective incident management may call for different ratios, depending on the type of incident, purpose of tasks, existing hazards, distance between personnel and resources etc. In cases where a supervisor's control is insufficiently effective, they can assign subordinate supervisors or redistribute subordinates.

4.2.1.7 Organization of incident facilities and locations

Depending on the incident size, complexity and situation, the Incident Commander, Unified Command, and/or EOC director organize the necessary support facilities. Typical facilities include the Incident Command Post, incident base, staging areas, camps, mass casualty triage areas, points-of-distribution, and emergency shelters.

4.2.1.8 Comprehensive resource management

Comprehensive resource management serves as a systematic and coordinated approach for the development and maintenance of mechanisms to identify requirements, order and acquire, mobilize, track and report, demobilize, and reimburse and restock resources such as personnel, teams, facilities, equipment and supplies.

Key resource management activities include:

— resource identification and typing;

— qualification, certification and credentialing of personnel;

— planning for resources;

— acquiring, storing and inventorying resources.

4.2.1.9 Integrated communications

Integrated communications allow incident response teams from diverse organizations to achieve incident management interoperability, share information and achieve situational awareness.

Incident managers facilitate communications through the development and implementation of common communications plans, interoperable communications processes and systems.

Integrated communications are necessary to:

— maintain connectivity;

— achieve situational awareness;

— facilitate information sharing.