EU-HIP
EU INTEROPERABILITY WITH HERA'S IT PLATFORM

Country visit report – Iceland

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ABBREVIATIONS TABLE

AI	Artificial intelligence
AMR	Antimicrobial resistance
API	Application Programming Interface
ATC	Anatomical Therapeutic Chemical
ATHINA	Advanced Technology for Health INtelligence and Action
BBLs	Broad-spectrum Beta-lactamase-producing pathogens
BOD	Biochemical oxygen demand
Bq	Becquerel(s) (unit)
BSL-3	Biosafety Level 3
CBRN(e)	chemical, biological, radiological and nuclear (and explosive)
CircaBC	EU communication and collaboration platform
CLP	Classification, Labelling, and Packaging
COD	chemical oxygen demand
CTBTO	Comprehensive Nuclear-Test-Ban Treaty Organization
DDD	Defined Daily Dose
DPA	Data Protection Authority
EARS-Net	European Antimicrobial Resistance Surveillance Network
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECURIE	European Community Urgent Radiological Information Exchange system
EEA	European Economic Area
EEA	European Environment Agency
EHR	Electronic Health Records
Eionet	European Environment Information and Observation Network
EMA	European Medicines Agency
EPRIMS	Emergency Preparedness and Response Information Management System
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
ESBL	Extended-spectrum Beta-lactamase
EU	European Union
EUDAMED	European database on medical devices
EudraGMDP	EMA database for manufacturing/distribution authorisations
EU-HIP	EU interoperability with HERA's IT Platform

EU-JAMRAI 2	Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections
EURDEP	European Radiological Data Exchange Platform
EURL-AMR	European Union Reference Laboratory for Antimicrobial Resistance
EWRS	Early Warning and Response System
FHIR	Fast Healthcare Interoperability Resources
GLASS	Global Antimicrobial Resistance and Use Surveillance System
HERA	EU Health Emergency Preparedness and Response Authority
HL7	Health Level 7
HRIS	Human Resource Information Systems
HROS	Human Resource Operating Systems
IAEA	International Atomic Energy Agency
ICD	International Classification of Diseases
ICE-SAR	Icelandic Search and Rescue
ICF	International Classification of Functioning, Disability and Health
ICG	Icelandic Coast Guard
ICNP	International Classification for Nursing Practice
ID	Identification
IEEA	Icelandic Environment and Energy Agency
IHR	International Health Regulations
IMA	Icelandic Medicines Agency
IMO	Icelandic Meteorological Office
IRSA	Icelandic Radiation Safety Authority
IT	Information technology
ITDB	Incident and Trafficking Database
LIS	Laboratory Information System
MAST	Icelandic Food and Veterinary Authority
MCM	Medical countermeasure(s)
MFRI	Marine and Freshwater Research Institute
MRSA	Methicillin-resistant Staphylococcus aureus
MS	Member State
NCIP	National Commissioner of the Icelandic Police
NCSP-IS	Nordic Classification of Surgical Procedures – Icelandic adaptation
NKS	Nordic Nuclear Safety Research
PCR	Polymerase Chain Reaction
PHPP	Pathogens with high pandemic potential

PM	Particulate matter
PPE	Personal protective equipment
RANET	Response and Assistance Network
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals
RSV	Respiratory syncytial viruses
SARI	Severe acute respiratory infections
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms
SSI	Statens Serum Institute
TESSY	The European Surveillance System
UNEP	United Nations Environment Programme
US	United States
VRC	Vancomycin-resistant enterococcus
WHO	World Health Organization
WOAH	World Organisation for Animal Health

INTRODUCTION

This report has been developed within the remit of the project EU interoperability with HERA's IT Platform (EU-HIP). EU-HIP is a consortium of 15 European countries, coordinated by Statens Serum Institute (SSI), Denmark. The scope of the project is to support countries to enhance and improve national IT systems in an efficient and coordinated manner, to obtain interoperability with the centralised IT platform of the EU Health Emergency Preparedness and Response Authority (HERA).

HERA's IT platform (ATHINA) is currently under development and seeks to gather intelligence on public health surveillance and medical countermeasures (MCM) to support threat assessment and crisis management across Europe. The priority areas are pathogens with high pandemic potential (PHPP), antimicrobial resistance (AMR), and chemical, biological, radiological and nuclear (CBRN) threats, as well as appropriate MCM, such as medicinal products, medical devices and personal protective equipment (PPE).

A baseline activity of the EU-HIP project was to perform a landscape assessment of countries' IT systems, in relation to the above-mentioned priorities, across all countries involved in the consortium. In addition, in-depth country visits were performed in a selected number of countries, to gain detailed insights on the countries' IT systems for health threat detection and assessment.

This report presents the findings from the landscape assessment and in-depth country visits in Iceland.

METHODOLOGY

For the gathering of the information presented in this report, a two-step methodology has been implemented. The overall results, based on the combined methodology, are presented in this report.

a. Landscape analysis

A data-gathering tool was developed by the EU-HIP consortium in close collaboration with HERA, to collect background information on countries' surveillance systems, covering the topics of digital infrastructures and systems, key actors and legislative aspects. By processing the material gathered through this tool, the EU-HIP team has produced an aggregated mapping of the current state of progress in national IT systems supporting collaboration on health threats preparedness and MCM in Europe (Deliverable 4.1 Landscape Analysis Report).

The tool was shared and supplemented with input from several national experts from different disciplines. This step aimed to gather an initial understanding of the information systems, stakeholders and legislations in place across the different European countries concerning HERA's priority topics.

b. Country visit

In the second phase, semi-structured interviews were conducted with experts, delving deeper into each topic included in the landscape analysis. The goal was to gain insights into the functionality of these systems, the roles and interactions of key stakeholders and additional details about pertinent legislations. The interviews built upon the landscape analysis tool's pre-existing questions, encouraging experts to provide additional information beyond what had already been shared during the first phase. The analysis of the information collected during the country visit was shared with the country of interest for review, and after approval, with HERA. The country was also encouraged to publicly share the report to benefit the wider community. Country-specific materials were also used to support further work within the EU-HIP project such as the identification of key areas of improvement (Deliverable 5.1 Country Needs Assessment report) and the actions needed to achieve interoperability with the upcoming ATHINA platform (Deliverable 5.3 National IT systems meeting interoperability standards).

As part of the country visit in Iceland, ten in-person and online interviews were performed in June 2024 over three days. An overview of the stakeholders interviewed can be found in Table 1.

***Table 1**. Overview of the stakeholders interviewed as part of the Icelandic country visit*

Interview date	Stakeholder
Monday 3rd June	Centre for Health Security and Communicable Disease Control – Vaccine monitoring
	Centre for Health Security and Communicable Disease Control and Icelandic Food and Veterinary Authority
	Centre for Health Security and Communicable Disease Control (IT Databases/Linkage/Data Sharing)

	National Centre for e-Health (at the Directorate of Health) (IT Digital/e-Health Infrastructure)
Tuesday 4th June	Icelandic Radiation Safety Authority
	Icelandic Environment and Energy Agency
	Landspítali – University Hospital (National Poison Information Centre and Department of Microbiology and Virology)
	National Commissioner of the Icelandic Police – Department of Civil Protection & Centre for Health Security and Communicable Disease Control
Wednesday 5th June	Centre for Health Security and Communicable Disease Control & Ministry of Health
	Ministry of Health & Centre for Health Security and Communicable Disease Control

Within the EU HIP project, the Sciensano and THL teams were responsible for conducting the interviews and writing the final report. The country visit was organised with the support of the Centre for Health Security and Communicable Disease Control at the Directorate of Health of Iceland for the identification of the stakeholders, planning of interviews, provision of additional explanation and revising the report when needed. During the discussions, the interviewers took notes that were summarised afterwards in the form of a report. The interviews were recorded and transcribed for minutes purposes.

RESULTS

I. Pathogens with high pandemic potential

a. Key actors and stakeholder networks

The **Ministry of Health** *(Heilbrigðisráðuneytið)* is responsible for the administration and policy-making in the field of health. The Ministry of Health supervises the national efforts in disease control and health security issues including patient rights, health insurance, laboratory licensing, national public health affairs and healthcare institutions. Regarding PHPP, the Ministry implements laws governing epidemics and communicable diseases. It decides, on the advice of the Chief Epidemiologist. and the National Committee on Prevention and Control of Communicable Diseases, which communicable diseases shall be notifiable, and which are subject to registration. In case of an epidemic caused by communicable diseases, the Ministry, on the advice of the Chief Epidemiologist, decides on the implementation of protective measures.

The **Directorate of Health** (*Embætti landlæknis*), operating under the supervision of the Ministry of Health, is the central authority responsible for public health, supervision of healthcare services and health promotion in Iceland. The Directorate oversees health surveillance, preparedness for public health emergencies and the Chief Epidemiologist advises the authorities regarding communicable disease control measures and prevention strategies. Under the Ministry of Health, the Directorate states operating licences for health care services, laboratories and healthcare professionals. Additionally, it is in charge of gathering and processing data on health and health services, as well as maintaining national registers on health, diseases and prescriptions.

For the current report, the key offices or centres of the Directorate of Health include the following:

- The **National Centre for e-Health** is responsible for the development and implementation of information technologies in the healthcare sector. It oversees the Directorate's information systems and works towards the digitalisation of health information registration. The Centre is responsible for operating *Hekla (cf. Pathogens with high pandemic potential – Data sources and systems)* .
- The **Centre for Health Security and Communicable Disease Control**, led by the Chief Epidemiologist[1], is responsible for the organisation, coordination and supervision of communicable disease control and prevention and immunisations throughout Iceland. In that regard, the Chief Epidemiologist is responsible for the Register of Communicable Diseases and the Vaccination Register. The Centre collaborates with the National Centre for e-Health focusing on developing new systems to manage health data, providing access and storage capacity to various databases and health information systems. Its main role is coordinating the public health response efforts against communicable diseases. In case of an epidemic, the Chief Epidemiologist advices the Ministry of Health and may apply emergency measures.

[1] *The Centre for Health Security and Communicable Disease Control is an unit operationally under the Directorate of Health, however the Chief Epidemiologist, head of the unit, answers directly to the Minister of Health under the Act on Health Security and Communicable Diseases (No.19/1997) (cf. Pathogens with high pandemic potential – Legislation and strategy).*

- The **Health Information Office** works across all other departments, ensuring integration and coordination of these efforts. The office is responsible for the organization and operation of the Directorate registers.

Several councils and committees are established, for health-related topics. For communicable diseases, the **National Committee on Prevention and Control of Communicable Diseases**[2], appointed by the Minister of Health, advised the health authorities on measures to prevent the spread of communicable diseases and their control. The Chair of the National Committee on Prevention and Control of Communicable Diseases is appointed by the Minister of Health and counts the Chief Epidemiologist as its secretary.

Landspítali – University Hospital is the national university hospital of Iceland and the leading hospital in the country. It is funded by the Ministry of Health. Notifiable diseases are treated both locally and in outpatient departments located at the Landspítali – University Hospital, including diseases in children. Landspítali – University Hospital hosts the Poison Information Centre and the Department of Microbiology and Virology.

The **Department of Microbiology and Virology** (*Sýkla- og veirufræðideild*) of Landspítali – University Hospital is a reference laboratory for Iceland in the fields of bacteriology, virology, mycology and parasitology as well as the main biology laboratory of Iceland and reference centre for respiratory viruses and gastroenteritis viruses. It supports the identification and diagnosis of patients being examined or treated due to infectious diseases or suspected infectious diseases. The Department works with the Chief Epidemiologist and other health authorities to improve public health through research and registration of infectious diseases, their causes and spread. This data is also used for preventive measures, such as infection control and vaccinations.

The **primary care health service** is organised through a network of primary care centres distributed across the country. Iceland is divided into seven health regions, each associated with a regional infection disease prevention doctor, appointed by the Minister of Health based on suggestions by the Chief Epidemiologist, whose role is to act as the main point of contact for the Centre for Health Security and Communicable Disease Control. The designated regional doctors are responsible for the local communicable disease prevention, for which the Chief Epidemiologist provides guidance, coordination, and informational resources. In case of an outbreak, the designated regional doctors ensure the coordination of the response in their region with the support of the Centre. If multiple regions are concerned, the Centre takes over the coordination of efforts across the regions.

The National Commissioner of the Icelandic Police, along with the **Civil Protection and Emergency Management Department** under his coordination, works closely with health authorities, oversees crisis management and support coordination to mitigate the impact of outbreaks *(cf. General Preparedness chapter).*

[2] *The Committee shall include seven specialists in the fields of communicable diseases, bacteriology, virology, sexually transmitted diseases and epidemiology, a community health physician and a nurse with specialist knowledge in the field of communicable diseases. Currently the committee, appointed for four years from September 2024 includes:*

- *The Chief Epidemiologist*
- *The director of the Icelandic Radiation Safety Authority*
- *The Chief Veterinarian and Senior Veterinary Officer a of the Icelandic Food and Veterinary Authority*
- *2 advisors of the Environment Agency of Iceland*

b. Digital infrastructures and systems

i. Data sources and systems

In regards to disease surveillance, the Centre for Health Security and Communicable Disease Control (hereafter '*the Centre*') hosts two databases: the Communicable Diseases Register and the Vaccination Register.

Communicable Diseases Register

Storage and management of health information related to communicable diseases are overseen by the Chief Epidemiologist and the Directorate of Health (hereafter '*the Directorate'*). The Chief Epidemiologist is responsible for maintaining the comprehensive Communicable Diseases Register. This register comprises all information collected related to notifiable diseases and those subject to registration, their causative agents and related events. They are either only subject to notification (*notifiable diseases*) or, if defined as a threat to public health, subject to registration (*reportable diseases*)[3].

a. *Notifiable diseases:* Physicians, laboratories, and healthcare institutions must submit data on notifiable diseases to the Chief Epidemiologist. Notifiable diseases reporting to the Chief Epidemiologist does not include personal identity information.
b. *Diseases subject to registration (reportable diseases):* Physicians, laboratories, and healthcare institutions must notify the Chief Epidemiologist of suspected or confirmed cases of a disease subject to registration. The reporting of these diseases to the Chief Epidemiologist includes personal identity information.

Information on disease cases comes from two primary sources: laboratory data and clinical data. Real-time data transfers are established between laboratory IT systems and the Communicable Diseases Register. Day-to-day patient sample diagnoses (PCR test results, blood or urine test results, etc.) for all diseases subject to registration, registered in laboratory systems, are automatically transferred via Health Level 7 (HL7) messages to the Communicable Diseases Register along with personal identity information. In addition, an excel file with additional information on selected pathogens (most of which are notifiable diseases) is received from the Department of Microbiology every week. This file does not include personal identity information.

Clinical diagnoses, of notifiable diseases and those subject to registration, are reported separately, using the International Classification of Diseases (ICD)-10 code registered in the Electronic Health Records (EHR). Electronic reporting to the Communicable Diseases Register occurs automatically within the system; when a specific ICD-10 code is entered, the data is transmitted directly without requiring any additional action from the physician.

Although these two data streams operate independently, they reside in the same database and can be interconnected when needed.

For clinical information, each case of diseases subject to registration should also be reported using a specifically designed form sent to the Chief Epidemiologist through a secure file

[3] *The lists of notifiable diseases and diseases subject to registration covered by the Act on Health Security and Communicable Diseases, are also available on the Directorate of Health website.*

transfer platform (*Signet transfer*)[4]. The information collected by the Centre from these forms is entered into a separate, non-integrated database.

The Centre currently receives hospital diagnosis data for severe acute respiratory infections (SARI), including influenza, COVID-19 and respiratory syncytial viruses (RSV) on ad hoc basis during the flu season by direct communication with the laboratories and Infection Prevention Control unit at Landspítali – University Hospital. While hospital discharge information is available and registered in the Hospital Discharge Register, hosted by the Directorate, it is not suitable for real-time monitoring due to a delay of several weeks, limiting its usefulness for tracking ongoing events but allowing continuous monitoring and year-over-year comparisons.

Vaccination Register

The Chief Epidemiologist is responsible for keeping a register of all vaccinations carried out in Iceland. To this end, the Centre holds the Vaccination Register, including personal identity information, which is used for participation in monitoring and risk assessment of a disease outbreak.

Physicians and nurses are obliged to register all vaccinations they perform into the EHR. Similar to clinical diagnoses (ICD-10 codes) of notifiable diseases and those subject to registration, data on vaccinations are automatically transferred from the EHR to the Vaccination Register.

The COVID-19 vaccination system, developed during the pandemic, operated independently from the broader Vaccination Register, tracking COVID-19 vaccinations and appointment registration. As the system was initially designed solely for COVID-19, it lacked the flexibility and sustainability to handle other vaccine registrations and is not in use anymore. A more versatile system is currently under development to accommodate all vaccination registrations. The objective of this system is its integration with the Icelandic patient portal, *Heilsuvera*, allowing individuals to access their vaccination information and e.g. to register for appointments.

Other systems and databases

The Directorate maintains various other health registers, including some pertinent to communicable disease surveillance. These registers collect data from the EHR of hospitals and healthcare institutions, on diagnoses, symptoms utilised for monitoring public health trends. Additionally, the Directorate maintains the Causes of Death Register, supplemented by data from the main civil registry of Iceland (held by Registers Iceland).

The National Centre for e-Health operates **Saga**, the primary patient electronic health record (EHR) system used in Iceland, which tracks electronic medical records. It is used by all major health institutions and clinics in Iceland. It documents patient information, health conditions, and interactions with healthcare professionals (the specific form for the reporting of diseases subject to registration is available through *Saga*).

Additionally, the National Centre for e-Health runs the patient portal, **Heilsuvera**. *Heilsuvera* is a secure website allowing patient communication with healthcare professionals. The most widely used feature is the ability to renew prescriptions. The portal also allows users to book

[4] *Efforts are underway to digitize the form, integrating it into EHR as a pop-up feature. While this may streamline reporting, completion remains voluntary, relying on the physician's discretion and the perceived significance of each case.*

appointments online and contact both inpatient and outpatient services. The Directorate, in collaboration with Icelandic primary healthcare centres and the Landspítali – University Hospital, provides public health information through *Heilsuvera*.

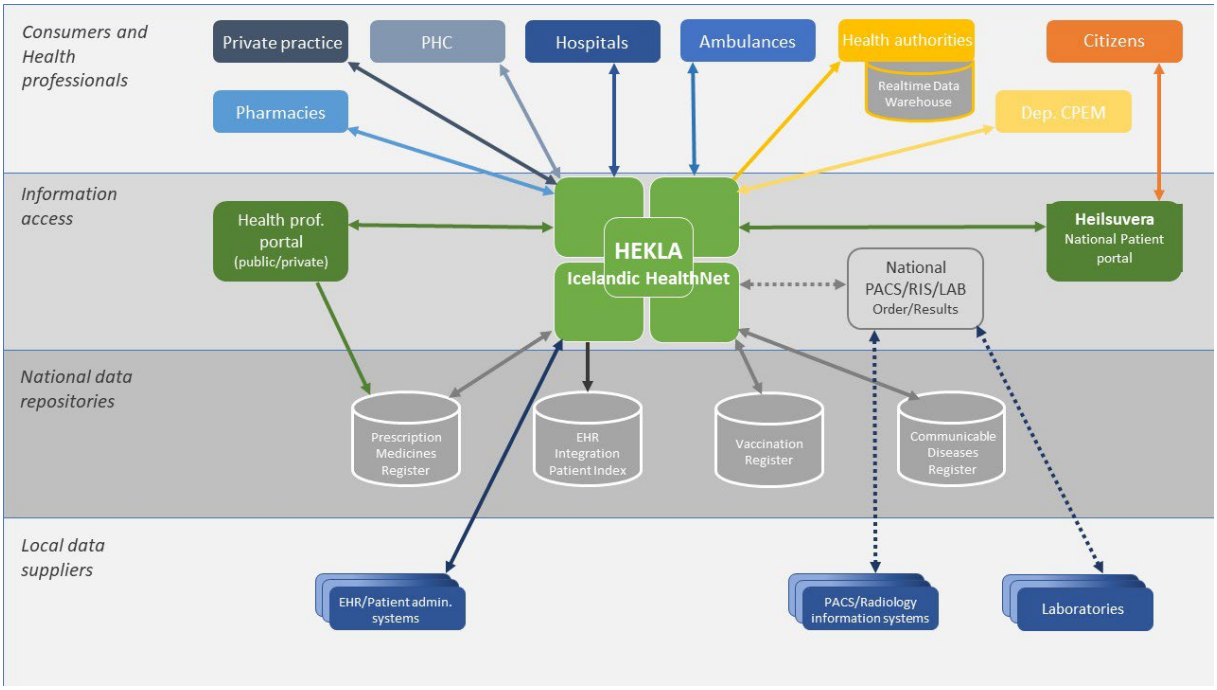
Iceland has interconnected electronic health records via the Icelandic healthcare network *Hekla*, operated by the National Centre for e-Health (Figure 1). *Hekla* is an electronic communication network for sending health data between entities and gathering information into centralised databases. All Icelandic health-related authorities, institutions and pharmacies are connected to *Hekla*, and electronic data is continuously collected from each healthcare centre infrastructure in Iceland and sent to registers/databases via *Hekla*. This integration enables a real-time, secure, standardized, and efficient transfer of electronic data between different software systems, as well as consolidating information into centralized databases.

Moreover, *Hekla* stores the following data[5]:

- Patient index (looks up where each patient´s health information is stored)
- Service index (locates where the patient has received health services)
- Patient´s vaccination
- Electronic prescriptions *(ePrescriptions)*
- Centralized medication card

Additionally, *Hekla* supports registries such as: the register of child custodians, the register of which primary healthcare clinic an individual is registered, the register of current licensed healthcare practitioners, the organ donor look-up service, the cancer screening laboratory results register, the birth notification service, and a few more.

Figure 1. *Healthcare digital infrastructure in Iceland*



CPEM: Civil Protection and Emergency Management; EHR: Electronic Heath Records; LAB: Laboratory; PACS: Picture archiving and communication system; PHC: Primary healthcare clinics; RIS: Radiology information system.

[5] *During COVID-19, Hekla also stored information on COVID-19 positive individuals and those in quarantine as well as vaccination certificates.*

The National Centre for e-Health is currently implementing a centralised medication card, a digital database storing up-to-date information on each person's current medications. Information in the centralised medication card will be stored in *Hekla*. Currently, one-third of the population is included, with full implementation expected by late 2025. The project involves collaboration with healthcare institutions to streamline prescription management. This system will consolidate medication information in one place, replacing the fragmented access patients and doctors currently have.

Secure clouds are not in place for communicable disease surveillance data in Iceland.

ii. Data linkage and data sharing

Data linkage for communicable diseases (diseases subject to registration) surveillance in humans is done through the national ID number (*kennitala,* akin to social security number), a unique ten-digit number. This is a personal identifier, widely used by different service providers in Iceland. All ID numbers are registered in the official civil registry held by Registers Iceland. The unique identifier is issued to all Icelandic citizens, and foreign residents and workers in Iceland upon registration (a temporary ID is given to tourists and short-term visitors if necessary, for instance if they seek healthcare or are admitted to a hospital).

Data linkage between registries within the Directorate (e.g. Vaccination Register, Causes of Death Register, Register of Primary Health Care, etc.) is done for surveillance purposes. Data linkage with external sources is possible, for specific research, but requires permission from the Data Protection Authority (DPA)[6].

All databases are connected to *Hekla* with each system having an active Application Programming Interface (API) to connect with other systems. The data transfer currently uses an XML format, however, the country is moving towards adopting Fast Healthcare Interoperability Resources (FHIR) standards. All systems connected to *Hekla* will eventually use FHIR, though complete implementation is expected to take several years.

The National Centre for e-Health maintains a metadata catalogue in *Hekla*. Researchers can access data through a structured process: the catalogue outlines available datasets, and with proper authorization from the Scientific Research Data Committee within the Directorate, they can obtain access to data for research purposes. However, this data is not classified as open data and requires a formal request for access for research purposes.

Iceland is involved in multiple European collaborations regarding communicable disease surveillance. Icelandic surveillance information are shared with The European Surveillance System (TESSy) of the European Centre of Diseases Prevention and Control (ECDC) gathering and monitoring system of infectious diseases and public health threats in EU/European Economic Area (EEA) Members states[7]. The data are sent to TESSy by the Centre.

[6] *An automation to obtain linked data of respiratory information (based on ICD-10 codes) and laboratory results of hospitalised patients is in progress.*

[7] *The Chief Epidemiologist is also the national contact point for the WHO's International Health Regulations, monitoring WHO warnings and assessing the need for epidemic prevention measures. She/he also reports events that may pose public health risks to the international community.*

iii. Standards and data quality

Centre for Health Security and Communicable Disease Control standards and control

A laboratory request must accompany each sample and can be provided either in a paper format (a standard form is available on the Landspítali – University Hospital website) or electronically through different health portals (Human Resource Information Systems (HRIS), Human Resource Operating Systems (HROS) or *Cyberlab*).

The Centre maintains regular communication with laboratories, overseeing data quality control checks before submission. Every three months, a review is conducted to ensure that all transmitted data in the Communicable Diseases Register has been received and processed accurately. HL7 messages, used for these transmissions, are complex and require specific decoding for system compatibility. An automated checklist identifies any unreadable data fields, which are manually reviewed on a weekly basis to detect potential issues. Occasionally, technical errors may prevent data from being received despite being submitted. Routine and periodic manual verification is performed to address these occasional issues and ensure data completeness and accuracy in the Communicable Diseases Register.

Clinical information is recorded following ICD-10 and SNOMED-CT terminologies standards.

Directorate of Health standards and control

By law, the Directorate of Health oversees electronic health records nationwide. This means that the Directorate is the coordinator of electronic health records and is responsible for, among other things, their administration, as well as the coordination, implementation and monitoring of their security, including the interconnection of health records and electronic communication. Once received, the Directorate is responsible for the cleaning and quality of the data in the registers under its supervision.

Standardized registration includes the coding of clinical information using internationally classification systems. The Directorate issues instructions on which classification system shall be used for the registration of health record information in health services in Iceland. All institutions and healthcare professionals who record information in the medical record must ensure that medical data is recorded correctly and the appropriate use of the classification systems prescribed by the Directorate for this purpose. This includes all doctors, all nurses and medical secretaries (various other health professions also need coded classification systems for registration).

All software used for the registration of health information shall at all times provide access to the current versions of the classification systems stipulated by the Directorate. The website SKAFL.is publishes current versions of the Directorate of Health's classification systems (including: ICD-10, the Icelandic adapted version of the Nordic Classification of Surgical Procedures (NCSP-IS), the International Classification for Nursing Practice (ICNP), International Classification and Functioning, Disability and Health (ICF) and SNOMED-CT[8]).

[8] *Detailed information about the Directorate of Health's classification system for healthcare can be found on the Directorate dedicated pages. Additionally, the Directorate of Health uses, in collaboration with IMA, the ATC classification system for medicinal products (Anatomical-Therapeutical-Chemical Classification) for all prescriptions for medicinal products registrations.*

The Directorate of Health established a Professional Council on classification systems in April 2016. The role of the Professional Council is, among other things, to formulate a policy on a coding system for the registration of information in health care in Iceland, to define and prioritize important tasks and to act as a professional advisor on coding issues. The Professional Council is composed of ten experts with decades of experience in coding issues in healthcare.

The Directorate is responsible for the translation, development, updating, publication and distribution of these classification systems in consultation with foreign controllers and their domestic users.

The Directorate has published guidelines, instructions and procedures regarding specific registrations, and updated in 2025 its instructions for the minimum registration requirements in first, second and third levels of healthcare services, enabling minimum coordinated registration by healthcare professionals. (for useful data collection and surveillance analysis by the Directorate).

Additionally, the Directorate requested the appointment of a '*quality manager*,' in each health institution and clinic, for the registration of health information. The '*quality manager*' is responsible for the promotion of registration in the health record in accordance with the provisions of laws, regulations and recommendations on minimum registration in health care in its facility; and also the implementation processes pertaining to standards and uniform registration.

iv. Reports

The Centre reports statistics on communicable diseases through visualisation supports (via Power BI tools) and overview reports. The Centre maintains an interactive dashboard on infectious diseases and one dedicated to the surveillance of Gonorrhoea, Chlamydia and Syphilis[9]. These dashboards are used for retrospective monitoring, as presented data are updated annually (quarterly for the Gonorrhoea, Chlamydia and Syphilis diagnoses data). Diseases subject to registration and notifiable diseases are also presented in Excel format annual reports.

Data relating to respiratory viruses (including COVID-19[10], influenza and RS-virus) are reported on a weekly basis during the winter season via a specific dashboard. They are subject of a weekly (or biweekly) communication (by means of a news/bulletin on the Directorate website[11]) on infection incidence and hospital admissions during periods of heightened activity[12].

Additionally, the Centre reports annually on participation in general childhood vaccination on a dedicated dashboard and in reports.

The Centre uses SAP Business Objects (Business Intelligence tool) to generate in-house reports as well as reports submitted to TESSy. These reports are pre-configured with the necessary variables, however, manual work is still required due to the limited availability of epidemiological information (e.g. transmission routes, travel history, food related history (if relevant), etc.), necessitating efforts to complete the reports by exporting data and manually filling in missing details.

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[9] *Gonorrhoea and Syphilis are closely followed due to a significant increase of cases in Iceland in recent years, as Chlamydia is monitored as the most common STI.*

[10] *During the COVID-19 pandemic, the Centre reported regularly on COVID-19 statistics, SARS-CoV-2 sequencing and COVID-19 vaccinations, via specific dashboards (Infogram dashboards and Microsoft Power BI dashboard) built for COVID-19 surveillance. These dashboards are no longer either available or updated.*

[11] *Through its multiples registers, the Directorate of Health reports regularly on statistics on public health and the activities of health services via interactive dashboards and reports.*

[12] *Winter period may vary from year to year; however, it typically starts around epidemiological week 40 and ends around week 20 of the following year.*

The Microbiology and Virology Department reports weekly and annually the number of cases caused by respiratory viruses and gastrointestinal viruses (total detections and total samples tested). Specific annual reports are also produced in regard to intestinal infections, invasive meningococcal diseases, Methicillin-resistant Staphylococcus aureus (MRSA) cases and Listeriosis. All reports are publicly available on the Landspítali – University Hospital website.

Additionally, frequent meetings (approximately every four weeks) between the Chief Epidemiologist and the Director General and lawyer in the Ministry of Health occurred to provide updates on ongoing matters and developments in regard to health monitoring.

v. Artificial intelligence (AI)

Currently, there's no AI-specific legislation in the country, but an Icelandic working group has been established to explore AI in healthcare, including potential regulations, and developed an AI Action Plan covering the 2024-2026 period. While Iceland does not plan to implement AI for diagnostics support, implementation options have been envisaged as supporting physicians by suggesting follow-ups with reminders (prescription renewal, suggestion for a test or an appointment for monitoring a medical condition, etc.) or for the security of personal information (identify misuses or suspect activities within patient medical records). On the surveillance aspect, AI could be potentially used in data analysis, report generation, and trend monitoring.

vi. Threat indicators

Threat detection, assessment and validation related to communicable diseases requires the involvement of experts. The regulation on reporting communicable diseases (No. 221/2012, last amended in 2023) defines the requirements for effective monitoring of communicable diseases:

- case notification by laboratory and physician (*notifiable diseases*)
- case notification by laboratory and physician with personal information (*diseases subject to registration*)
- case notification required only from the laboratory (*diseases subject to registration*)
- case notification required only upon hospital admission (*diseases subject to registration*)

In terms of day-to-day activities, laboratories and physicians work in close collaboration with the Centre. They are responsible for the immediate notification of a threat to the Chief Epidemiologist if identified or suspected.

Iceland also conducts syndromic surveillance by including certain symptoms in its list of notifiable cases and those of diseases subject to registration. This approach enables disease monitoring outside laboratory testing and complements overall surveillance efforts. Additionally, legislation mandates the reporting of new and unexpected cases facilitating the rapid detection of unforeseen events. However, concerns remain that syndromic monitoring, in its current process, may not be timely enough to identify early signs of disease outbreaks.

Recently, the Chief Epidemiologist has updated the published guidelines for clinical reporting of cases of diseases subject to registration, with emphasis on contact-tracing considerations. The guidelines indicate, per disease subject to registration, the disease/pathogen diagnosis method, specific recommendations when notifying the Chief Epidemiologist, recommendations

or implementing contact-tracing research, and the need to notify the local health department and other relevant institutions.

Additionally, the Chief Epidemiologist maintains an electronic newsletter on communicable diseases in Iceland, EPI-ICE, which discusses trends in infectious diseases, vaccinations, and the main events that have occurred in recent months.

In case of a severe threat, the Microbiology and Virology Department operates a Biosafety Level 3 (BSL-3) laboratory designed for the study of infectious agents or toxins capable of causing severe or lethal infections. The department's personnel are specially trained to handle high-risk or unknown threat samples, adhering to strict protective protocols. Although no dedicated contact number is assigned for emergencies, the Microbiology and Virology Department remains accessible at all times in the event of a potential threat detected.

The Microbiology and Virology Department also cooperates with foreign institutions. Within the development of the sequencing process, the department collaborates with SSI (Denmark) to facilitate training and the transfer of technical expertise and knowledge of this component of microbiology. The Directorate of Health (the Chief Epidemiologist) also owns a formal contract with the Public Health Agency of Sweden (*Folkhälsomyndigheten*) for analysis of category 4 pathogens part of the microbiology surveillance. This agreement includes access to a 24/7 hotline for consulting Swedish microbiologists on specific cases, diagnosis confirmation for potential biothreats, and risk analysis. Additionally, negative result samples can be sent to Sweden for further verification and confirmation.

By law, a National Committee on Communicable Diseases shall advice the health authorities on policy measures against communicable diseases to prevent the spread of communicable diseases. Additionally, the Minister of Health appoints a special collaborative committee to supervise necessary measures for assessing and eliminating infection risks or risks posed by animals, food, water, sewage, or other environmental factors capable of spreading infectious agents or any agents threatening human health. The Chief Epidemiologist and the Icelandic Environment and Energy Agency (IEEA), the Icelandic Radiation Safety Authority (IRSA) and the Icelandic Food and Veterinary Authority (MAST), meet ad hoc if the matter falls within their ambit[13]. The Chief Epidemiologist is responsible for the epidemiological analysis and risk assessment of unexpected events that fall under the disease monitoring aspects. She/he conducts an epidemiological investigation when a biological threat is suspected.

Retrospective overview of actions implemented within the COVID-19 epidemiological context

Due to its context, the COVID-19 crisis has seen the implementation of multiple initiatives and emergency measures by the health authorities.

The National Centre for e-Health was responsible of the implementation of the multiple IT initiatives to support COVID-19 prevention and monitoring strategies (at the exception of the quarantine system)[14].

[13] *This Committee consists of the Chief Epidemiologist, who is also the chair, two persons appointed by the Icelandic Food and Veterinary Authority, one of whom is a specialist in food safety and the other is a specialist in zoonotic diseases, one person from the Radiation Agency and two persons from the Icelandic Environment and Energy Agency, one of whom is a specialist in food safety and the other is a specialist toxic chemicals.*

[14] *Some IT initiatives were not operational in time to achieve full effectiveness. Certain systems, including the Bluetooth contact tracing app designed to identify contacts of confirmed cases, were developed but were not widely deployed due to various development challenges before the pandemic's urgency decreased.*

The Directorate integrated a symptom-reporting feature into Heilsuvera, enabling individuals to assess their need for COVID-19 testing. This feature helped individuals determine whether they required a test but also assisted in managing crowds at testing sites. If the assessment indicated that a test was indicated, a specific barcode was provided to individuals.

The Directorate, in collaboration with the Centre, implemented a research system within the Prescription Medicines Register to identify priority groups based on medical conditions and ICD-10 codes, ensuring (at-risk) individuals received targeted vaccination invitations. These invitations, whether for priority groups or as part of the age-based vaccination strategy, were sent via SMS with designated appointment times and locations. Vaccination appointments were confirmed through online registration, where individuals provided identification details and received a barcode along with further safety instructions.

The Centre put in place a new, easy-to-use, system for COVID-19 vaccination registrations (due to a lack of flexibility of the general vaccination registration system), enabling rapid registration and messaging options for vaccination invitation for practicians.

Additionally, a communication support system has been developed by the Centre, featuring automatic SMS notifications for positive test results, quarantine instructions, and the submission of contact-tracing forms. Individuals who had contact with a positive case were also notified automatically. After seven days, they would receive an invitation for testing, including a specific barcode, allowing them to be released from quarantine if their test result was negative.

To guarantee full compliance with data privacy regulations, the Directorate maintained constant communication with the DPA in regard to the implemented initiatives and ensured that thorough safety checks were carried out.

The Microbiology and Virology Department of the Landspítali – University Hospital enhanced its detection capabilities by acquiring new equipment, enabling an increase in testing capacity when needed.

c. Legislation and strategy

The Act on Health Security and Communicable Diseases (No.19/1997, amended several times but notably in 2021 to strengthen legal background of COVID-19 measures, last amended in 2024) guarantees the general communicable disease prevention measures in Iceland. The Act covers diseases and pathogens that can cause epidemics and threaten public health, as well as other serious susceptible diseases[15], unusual and unexpected events that can have serious health consequences for the general public. It outlines the responsibilities of national and local health-related authorities and professionals in disease prevention, monitoring, and response in regard to health-related risks for the Icelandic population.

It defines the roles of the Directorate of Health, the Chief Epidemiologist and the district medical officers for communicable disease control, appointed by the Ministry of Health and under the supervision of the Chief Epidemiologist, responsible for public health prevention within their district[16]. The Act enacts the composition and roles of the National Committee on Prevention and Control of Communicable Diseases as an advising committee to the Ministry of Health, and the close collaboration with other authorities when a matter falls within their ambit.

Among the last amendments (No.2/2021) of the Act, emphasis is placed on contact-tracing initiatives from physicians and the Chief Epidemiologist, especially the processing of sensitive personal data for the purpose of serious health threat surveillance. The amendment stresses the conduct of the epidemiological investigation and the appropriate initiation of contact tracing. The Chief Epidemiologist should ensure that the sharing of personal data for screening, epidemiological investigation or contact tracing is carried out in a secure manner (e.g. encrypting data, using pseudonyms, access controls and activity logging). Emphasis was also placed on the conditions under which quarantine and isolation measures are put in place and the authorities responsible for enforcing them, to prevent the spread of infection.

The Act also defines the authorities responsible for cross-border measures and examination for disease control, in the event of a risk of epidemics being transmitted to or from Iceland.

The Regulation on reporting of communicable diseases and agents posing a threat to public health (No.221/2012, last amended in 2023), defines the establishment and maintenance of a comprehensive Communicable Diseases Register that includes data on infectious diseases, their causative agents, antimicrobial consumption, and vaccination records. It mandates physicians, laboratories, hospital wards and healthcare institutions to report information on communicable diseases to the Chief Epidemiologist. The regulation specifies the lists of *notifiable* diseases and *diseases subject to registration*, and the condition of reporting for some diseases subject to registration.

The Regulation on Vaccination in Iceland (No.221/2001, last amended in 2024) outlines the vaccination practices in Iceland. It mandates that all vaccinations administered within the country be registered in the vaccination database maintained by the Chief Epidemiologist. The regulation stipulates children and adult general vaccinations, and those free of charge. It reiterates the details of the reporting of vaccinations by those who administer the vaccines. The last amendment (No.1534/2024) provides the latest schedule of free-of-charge vaccinations for children (age at vaccination, diseases/pathogens covered and vaccine name).

[15] *'Diseases' refer to diseases or contagions caused by infectious agents, microorganisms or parasites, as well as serious health consequences caused by toxins and radioactive substances.*

[16] *Spatial division of the district medical officers' areas are described in the Regulation on the appointment of chief physicians of health care centres to carry out communicable disease prevention (No.387/2015)*

The Regulation on infection prevention control measures (No.817/2012, last amended in 2024), complementing the Act on Health Security and Communicable Diseases(No.19/1997, last amended in 2024), details protocols and measures in place in Iceland for managing a case of communicable disease subject to registration. It specifies the roles and responsibilities of the Landspítali – University Hospital and primary healthcare providers. Additionally, the regulation briefly addresses the requirement of a safety stock of medicines and other medical equipment (including PPE) of the Chief Epidemiologist and defines Iceland's key points of entry for infection control[17].

The Regulation on the activities of laboratories engaged in the diagnosis of diseases covered by the Act on Health Security and Communicable Diseases (No.415/2004, last amended in 2023) governs licensing and activities related to laboratories engaged in the diagnosis of diseases covered by the Act.

Individuals' medical information is regulated by two legislations: the Act on Health Records (No.55/2009, last amended in 2024) and the Regulation on Medical Records (No.550/2015). The Act on Health Records establishes comprehensive guidelines for the creation, management, and confidentiality of health records in Iceland, ensuring the privacy and security of individual's sensitive health information. It mandates that health records be maintained accurately and securely, ensuring that only authorized personnel have access. It also stipulates the obligation for healthcare professionals who receive patients for treatment to keep a record of medical information and registered specific information in it. Patients are granted rights to access their own health records and to be informed about who has accessed their data.

The Regulation on Medical Records provides detailed directives to support the implementation of the Act on Health Records. It specifies the standards for the content and structure of medical records, ensuring consistency and completeness across healthcare providers. It outlines the procedures for documenting patient information. The Regulation also reiterates the security measures required to protect health records from unauthorized access, alteration, or loss. Additionally, the Regulation delineates the responsibilities of healthcare practitioners in maintaining and updating medical records, as well as the protocols for granting access to authorized individuals.

Last amendment of the Act on Health Records (No.96/2024) introduces the possibility to a patient to share defined health record information in countries in the European Economic Area (including general information about the patient, information on diagnoses, active treatment, surgery, ongoing drug treatment and vaccinations, as well as information on allergies, pregnancy and implants). This amendment assigns responsibility to the Directorate of Health for operating a national health information portal to enable the sharing of certain key information defined from medical records and authorises it to store centrally the information needed to enable dissemination (*cf. Act on the Directorate of Health No.41/2007*). These two legislations, in addition of the Act on the Directorate of Health and Public Health (No.41/2007, last amended in 2025), support the work of the Directorate of Health by the extensive registration of health-related data by healthcare professionals. Sequentially, the Act on the Directorate of Health and Public Health stipulates the responsibility of organisation, modalities

[17] *Based on legislation, key points of entry are the terminal at Keflavík Airport and the ports of Reykjavík, Grundartangi, Seyðisfjörður, Akureyri and Ísafjörður.*

and maintenance of national records on health, diseases, accidents, prescriptions, births, and the activities and results of the health service by the Directorate of Health.

Furthermore, related to the patient information, the Directorate is responsible, by the Medicinal Products Act (No.100/2020, last amended in 2024), for the operation of the new centralised medication card (*cf. Pathogens with High Pandemic Potential chapter – Data sources*). The Directorate should ensure that patients, healthcare professionals involved in treatment and pharmacists dispensing medications, have access to these records through the new centralised medication cards. The minister may issue a specific regulation on the centralized database, including provisions on access, the type of information recorded, and data handling procedures.

In 2019, the Icelandic Ministry of Health published a National Health Policy for health services until 2030. The main goals focus on building a strong, efficient, and patient-centred healthcare system, where key principles include:

1. **'*Leadership for Results*'**, the role of service-providers, central and local, are well defined to ensure effective implementation of healthcare policies.
2. ***'The Right Services in the Right Place'***, equal accessibility, as well as an appropriate distribution of healthcare services is achieved across Iceland (through distance healthcare and patient transport services).
3. **'*People in First Place*'**, patient-centred care is prioritized and user experience in healthcare institutions is improved.
4. **'*Active Users*'**, everyone has access to their own medical records to encourage individuals to take an active role in their own health-related decisions and improve individual health literacy
5. ***'Efficient Service Purchasing',*** resource allocation and funding models are optimized to improve efficiency and reduce the patient's share of costs.
6. **'*Quality First*'**, high-quality standards and safety measures across the healthcare system are implemented.
7. **'*Thinking About the Future*', ** investments are made in healthcare innovations, workforce development and research.

The policy is implemented by means of five-year action plans and reviewed annually to ensure continuous improvement.

In addition, the Directorate of Health and the Centre published their annual work plan alongside a comprehensive annual report, covering all health-related areas in which the Directorate is involved. The work plan outlines objectives for the Directorate's four main areas of supervision (health policy, infection prevention control, public health, and internal operations) specifying a scale, assessment methods, and target measures for each objective. In regards to health information and communicable diseases, the 2023-2024 work plan, focused on:

- The prescription monitoring based on pro-active use of the Prescription Medicines Register
- Metadata standardisation about variables in health records
- The increase in the availability of electronic healthcare solutions for the Icelandic population
- The vaccination participation against COVID-19 and influenza and increased participation in general vaccinations for 1- and 4-year-old children
- An increased focus on measures against the spread of sexually transmitted diseases

- The rational use of antibiotics outside hospitals and strengthening the monitoring of antibiotic use in healthcare institutions
- Updating and exercising preparedness plans for health emergencies[18]

Regarding preparedness, the Pandemic National Plan – 3rd Edition (2020) provides a structured response to pandemics, supporting coordination between public health authorities and emergency response agencies. It is based on the Civil Protection Act (No. 82/2008) and the Act on Health Security and Communicable Diseases (No.19/1997). The plan initially focused on pandemics caused by influenza but was expanded to cover all types of pandemics in 2020. It applies to all individuals in Iceland, including those at airports and seaports, with provisions for activating localized response plans at those sites. Its main objectives include:

- Delaying or preventing the entry of an epidemic/pandemic into Iceland
- Minimizing infection risk and the spread within the country
- Support and maintaining essential services and infrastructure
- Ensuring coordinated actions and communication to all providing essential services and the public
- Providing medical treatment and support
- Enhancing surveillance and outbreak detection
- Monitoring during the epidemic/pandemic

The Chief Epidemiologist and the National Commissioner of the Icelandic Police (NCIP) are responsible for activating the plan. It follows a three-tier response system (uncertainty, alert, emergency[19]). The Icelandic government, Chief Epidemiologist, and Civil Protection authorities coordinate the pandemic response.

There is ongoing collaboration also among the Nordic countries in the areas of communicable diseases, vaccination strategies, and health security, including preparedness efforts. This cooperation takes place through both regular meetings and specific joint initiatives, some of which are facilitated by frameworks such as the Nordic Council. While certain aspects of this collaboration are formalised, others remain informal in nature.

Finally, at the institutional level, Iceland´s main actors have defined and are implementing improvements for the surveillance of communicable diseases. Some include:

- The Centre secured a new grant from the EU4Health programme, aimed at enhancing the digital infrastructure supporting communicable disease surveillance. The focus is on improving digital systems, including notifications from physicians and streamlining the flow of diagnosis and epidemiological data. Also, a new contact tracing platform is to be built. One of the goals is to increase automation in the reporting process, particularly for reporting to ECDC. This will include the strengthening of automating checks, improving reporting efficiency, and better integration of the systems for testing and surveillance. These efforts are intended to minimize data gaps and enhance the completeness of epidemiological information, thereby increasing its reliability for reporting on various diseases.

[18] *Official communicable diseases control measures and their preparation are carried out in cooperation between the Chief Epidemiologist and the Civil Protection Department of the National Commissioned of the Icelandic Police, based on the Regulation on infection prevention control measures (No.817/2012).*

[19] *Roles and dedicated actions related to the three-tier response system are defined in the CBRNe National plan.*

- Vaccination monitoring is also targeted through the EU-HIP grant, with the enhancement of the vaccination registration system, strengthening the Vaccination Register. These initiatives aim to streamline data processes, improve system interoperability, enhance monitoring of vaccine preventable diseases, and optimize vaccination management overall. The main objective focuses on enhancing the Vaccination Register by improving its organisation, reliability, consistency and interoperability with other health systems/registers, for a comprehensive reporting of vaccination data. As a support, a new vaccination registration system aims for daily, widespread, and reliable reporting by providers.

Both initiatives have secured the financial resources needed for their development and implementation. However, they are currently constrained by the limited personnel available.

In addition, the Microbiology and Virology Department has started the development of its sequencing capacities and building on Icelandic data (COVID-19 and other pathogens) to improve pathogen surveillance. This activity is not operating on a regular basis, so currently, no information is publicly reported[20].

[20] *The Microbiology and Virology Department as the willingness to also improve the development of the wastewater surveillance in collaboration with the Icelandic Energy and Environmental Agency handling the environmental sampling for the foodborne surveillance.*

II. Antimicrobial resistance

a. Key actors and stakeholder networks

The **Ministry of Health** *(Heilbrigðisráðuneytið),* in addition to its responsibilities and supervision regarding communicable diseases (*cf. Pathogens with high pandemic potential chapter*) which include AMR-related pathogens, is responsible for setting overall regulations of medicinal products and devices in Iceland. The Ministry supervises the operations of the Icelandic Medicines Agency (IMA) related to medicinal and related products. The Ministry may issue a regulation setting out more detailed rules on the prohibition or restriction of the use of antibiotics for human use. In August 2024, the first One Health AMR National Action Plan (NAP), was implemented in Iceland and covers years 2025-2029.

The **Icelandic Medicines Agency** (IMA – *Lyfjastofnun*) is the regulatory authority responsible for overseeing the import, distribution and regulation of medicines and medical devices in Iceland. It ensures the quality, safety and availability of medicinal products, as well as monitoring medicines sales in Iceland.

The **Directorate of Health** (*Embætti landlæknis*), operating under the supervision of the Ministry of Health, is the central authority responsible for public health and health promotion, and monitoring of safety and quality of healthcare services in Iceland. The Directorate oversees health surveillance and public health emergency preparedness. It has the responsibility to monitor the prescriptions and promote reasonable use of medicinal products. The Directorate of Health is responsible for the Prescription Medicines Register, including prescriptions and dispensations of antibiotics.

The **Centre for Health Security and Communicable Disease Control***,* at the Directorate of Health led by the Chief Epidemiologist, is responsible for the organisation, coordination and supervision of the communicable disease control and prevention throughout Iceland. In that regard, the Chief Epidemiologist is responsible for maintaining the Register of Communicable Diseases, keeping records of AMR-related cases. Complementary, the Chief Epidemiologist at the Directorate hosts a register of human consumption of antimicrobial agents in Iceland. Its main role is coordinating the public health response efforts against communicable diseases.

The **Department of Microbiology and Virology** (*Sýkla- og veirufræðideild*), hosted at Landspítali – University Hospital, is a reference laboratory for Iceland in the fields of bacteriology, virology, mycology and parasitology. It supports the identification and diagnosis of patients being examined or treated due to infectious diseases or suspected infectious diseases. It works with the Chief Epidemiologist and other health authorities to improve public health through diagnoses and registration of infectious diseases and their causes. This data are also used for preventive measures, such as infection control. The Department is the national reference laboratory for AMR surveillance in humans.

Physicians, are obliged to register data on notifiable diseases and diseases subject to registration, according to the law and instructions given by the Chief Epidemiologist. The same applies to directors of laboratories, directors of healthcare departments, and institutions. To support the Chief Epidemiologist in recording antimicrobial consumption, directors of healthcare institutions are obliged to submit information on the use of antimicrobial agents within their institutions (broken down by departments), following instructions provided by the Chief Epidemiologist.

The **Icelandic Food and Veterinary Authority** (MAST – *Matvælastofnun*), under the Ministry of Food, Agriculture and Fisheries (*previously: Industry and Innovation*), is the competent authority in Iceland in the field of food safety, animal health and welfare, plant health and water for human consumption. MAST is responsible for monitoring and reporting on resistance to antibiotics detected in animals, animal products or food. The AMR surveillance in animals is organised in close collaboration with the national reference laboratory: the Division of Bacteriology, Parasitology, and Pathology at the University of Iceland's Institute for Experimental Pathology at Keldur.

b. Digital infrastructures and systems

i. Data sources

Monitoring of antimicrobial use (AMU) and resistance (AMR) in Iceland is organised across two domains: the human health sector and the veterinary sector.

Infections in humans and antimicrobial susceptibility

Laboratory antimicrobial testing on human clinical samples is conducted in all seven health care regions in the country. The Department of Microbiology and Virology at the Landspítali – University Hospital is the national reference laboratory (NRL), responsible for susceptibility testing and AMR reporting in humans. The monitoring of microbiological invasive isolates is based on routine diagnostics (hospital screening process) and the investigation of specific clinical samples.

Data on human cases relevant to AMR surveillance are maintained across multiple registries. The Communicable Diseases Register contains reported laboratory test results and clinical data, including personally identifiable information for cases involving a disease subject to registration. Supplementary data, such as vaccination status, are recorded in the Vaccination Register *(cf. Pathogens with high pandemic potential – Data sources).*

A standardized procedure for reporting cases, including notifiable and diseases subject to registration, is in place (*cf. Pathogens with high pandemic potential chapter*). Selected information on cases of AMR-pathogens subject to registration (including *Methicillin-resistant Staphylococcus aureus* (MRSA), *Vancomycin-resistant enterococcus* (VRE) and *Extended-spectrum Beta lactamase (-producing gram negative bacteria)* (ESBL)) are reported directly by the Department of Microbiology at Landspítali – University Hospital and the Clinical Laboratory at Akureyri hospital, that send electronic data from their laboratory information system (LIS) to the Communicable Diseases Register[21] which is used for analysis and reporting. All isolates of AMR-pathogens subject to registration are sent to the Department of Microbiology and Virology at Landspítali – University hospital for confirmation. For other resistant pathogens, voluntary cooperation exists between the smaller laboratories in the seven healthcare regions and the national reference laboratory at Landspítali – University Hospital. Notifications to the Chief Epidemiologist are made by physicians, laboratories and hospitals/clinics.

Results from the Department of Microbiology and Virology at the Landspítali – University Hospital and the Clinical Laboratory at Akureyri hospital are routinely and automatically reported to the Register of Communicable Diseases for AMR-pathogens subject to registration. All information is collected at the national level.

Antimicrobial use in humans

The monitoring of the human consumption of antibiotics is based on three data sources: antibiotic sales from the Icelandic Medicines Agency (total sales and hospital sales), the antibiotic prescriptions in the community (Prescription Medicines Register) from the Directorate

[21] *Microbiological and clinical laboratories register their results in their own information system. Only selected data is submitted to the Communicable Diseases Register. Only Landspítali – University Hospital and Akureyri hospital laboratories send digital data on AMR and notifiable diseases directly to the Register. Smaller laboratories in Iceland send isolates for confirmation to Landspítali – University Hospital, which sends the notification to the Communicable Diseases Register.*

and the antibiotic use in healthcare institutions send directly to the Chief Epidemiologist (Antimicrobial Consumption Register).

Information on antibiotic use and prescriptions, outside healthcare facilities, is collected in the Prescription Medicines Register, at the Directorate[22]. This database contains real-time information on all prescribed pharmaceuticals dispensed outside hospitals and collects only non-personally identifiable data on medication prescriptions. The register includes data received through the electronic transmission of prescribed pharmaceuticals issued by healthcare professionals via *Hekla* and electronic transmissions from pharmacies, as well as machine dosing of medications for nursing homes. However, the register does not include details on individual prescriptions and medication administration documented on paper or within the internal electronic systems of hospitals and other healthcare institutions or nursing homes.

Data on antibiotic use in hospitals is recorded by IMA based on information provided by wholesalers under reporting obligation. Unlike other hospitals, Landspítali – University hospital provides its antibiotic sales data directly to IMA. Antibiotics that are not marketed in Iceland but are available through exemptions are reported separately from marketed antibiotics IMA's sales figures but are included in the prescription data from the Directorate of Health's Prescription Medicines Register.

Antibiotic susceptibility in animals

Monitoring and reporting according to Decision (EU) 2020/1729 on antimicrobial resistance in animals and food is under the responsibility of MAST (including the surveillance of *Salmonella, Campylobacter*, *E.Coli* bacteria, *ESBL/AmpC/carbapenemase-producing E. Coli* and MRSA). Targeted screening studies are performed to detect specific AMR pathogens in animals and food. This surveillance is in collaboration with the Department of Microbiology at the University of Iceland's Institute for Experimental Pathology at Keldur, which is the national reference laboratory for AMR in animals and conducts all susceptibility tests of bacterial strains from animal and food samples. Data on AMR of bacteria from animal samples and food are stored at Keldur and shared with MAST.

No digitalised system is fully implemented for data collection and used for AMR monitoring in animals.

Antimicrobial use in animals

IMA systematically records data on the sale of antibiotics for veterinary use. Although the information is categorized by antibiotic classes, it is currently not feasible to disaggregate the data by specific animal species[23].

Additional surveillance of AMR is conducted in Iceland by IEEA. The agency carries out regular surveillance of substances in water, including medicines. Through a screening process of

[22] *Discussion are currently underway on an amendment to the law being put forth in Parliament by the Minister of Health to allow the Directorate of Health to collect the use of antibiotics from healthcare institutions into the Prescription Medicines Register (along with other data on medicinal consumption).*

[23] *The Icelandic Food and Veterinary Authority manages a health database in which veterinarians are expected to record diagnoses and medications for cattle and horses. However, this registration is not mandated by regulation, resulting in inconsistent data entry. Consequently, the data on antibiotic use for these species is considered unreliable. An enhanced system, which will be more accessible and include more animal species, is currently being developed.*

substances on the European Union (EU) watchlist, in samples of waterways, the IEEA aims to monitor antimicrobial residues in the environment.

No AI solutions are currently evaluated for AMR surveillance (whether for antibiotics resistance susceptibility cases or sales of antibiotics) in Iceland. Secure clouds are not in place for AMR surveillance data (whether for information on human cases, animals or medical products) in Iceland.

ii. Data linkage and sharing

As described for pathogens with high pandemic potential, data linkage for AMR surveillance in humans is done through the national ID number (*kennitala*), a unique ten-digit number (*cf. Pathogens with high pandemic potential – Data linkage and sharing*).

Iceland is involved in multiple European and international collaboration projects in regard to AMR. Icelandic AMR surveillance data are shared with The European Surveillance System (TESSy/Epipulse) of the ECDC, which reported information to two ECDC's AMR-related projects: the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) and The European Antimicrobial Resistance Surveillance Network (EARS-Net). AMR surveillance data in humans are also shared with the WHO's surveillance system: Global Antimicrobial Resistance and Use Surveillance System (GLASS).

Keldur is a part of the EURL-AMR network and regularly participates in proficiency tests as an external quality check.

Iceland is part of numerous OneHealth collaboration projects in regard to AMR monitoring, including:

- The Nordic One Health strategy and expert groups (under the Nordic Council), a group that focuses on antibiotic resistance, vaccines, rare antibodies, and anti-toxins
- The EU AMR One Health Network team
- The United Nations Environment Programme (UNEP)
- The World Organisation for Animal Health (WOAH)
- The Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI 2), aims for action against the spread of AMR in people, animals and the environment. The project concerns antibiotic stewardship, infection prevention, monitoring, access to antibiotics and raising awareness on antibiotic resistance

iii. Standards and data quality

For human surveillance, within the Communicable Diseases Register, standardised terminologies and classification systems are used for the capture and reporting of information about diagnoses and treatments. For notifiable diseases related to AMR, the ICD-10 classification system is used.

Antibiotic use in humans is classified and reported using the Anatomical Therapeutic Chemical (ATC) classification[24], which is also employed by IMA for recording antibiotic sales.

[24] *Including the 'J' subcategory of the Anti-infectives for systemic use section, and others antimicrobials from ATC categories other than 'J' : 'A' code of Digestive system and metabolism section, 'D' code of Skin medicine, 'G' of Urinary and genital tract section and 'P' of Antiparasitic section.*

Antibiotic sales for animals are classified using the adapted ATC classification for veterinary use (Anatomical Therapeutic Chemical Classification System for veterinary medicinal products (ATCvet)[25]).

No metadata catalogue is currently available for AMR data (whether for information on human cases, animals or medical products) in Iceland.

iv. Reports

Monthly to yearly updates of laboratory cases of AMR-pathogens subject to registration are accessible through the Infectious Diseases dashboard of the Directorate of Health and comprehensive annual data are compiled in annual reports on antibiotic use and antibiotic susceptibility in humans and animals in Iceland.

Yearly data on antibiotic use (under the ATC *'J'* categories) in humans is available via a dashboard managed by the Directorate of Health, which contains data on all human medication prescriptions outside hospitals.

v. Threat indicators

Threat detection for AMR is event-based or indicator-based, depending on the specimen concerned. Detection, assessment and validation of a threat always involve experts.

The surveillance of AMR cases is defined in a One Health approach, where the institutions responsible for monitoring human and animal cases are in regular communication. Today, reporting of a threat from one surveillance system to another is carried out by telephone and/or email by experts.

For the human sector, national guidelines for screening, infection tracing and infection control for antibiotic-resistant pathogens (here, ESBL, MRSA and VRE) in healthcare services have been produced. AMR cases that are notifiable or subject to registration are reported for each patient in the *Snowflake* electronic alert system in *Saga* patient information system. The information registered and previously diagnosed on antibiotic resistant pathogens are accessible to other healthcare and public health institutions.

For the animal sector, national plans for prevention and responses related to specific AMR-related pathogens (*Salmonella* and *Campylobacter*) in specific settings (poultry and pig farms and products) have been produced to ensure safety and consistency in monitoring AMR-pathogens. These plans are supported by guidelines for good practices regarding surveillance, registration, traceability and record-keeping.

[25] *ATCvet codes are created by placing the letter 'Q' in front of the ATC code of most human medications. The structure of the subclasses is similar to that of the ATC system.*

c. Legislation and strategy

The Act on Health Security and Communicable Diseases (No.19/1997, last amended in 2024) outlines the responsibilities of national and local authorities in disease prevention, monitoring, and response in regard to health-related risks for the Icelandic population. The Act mandates regular monitoring, surveillance and reporting of certain communicable diseases by healthcare professionals and institutions, including AMR pathogens. It also stipulates the implementation of the International Health Regulation (IHR), as Iceland's health authorities are required to cooperate with international bodies and other nations in managing cross-border health threats.

Additionally, the Regulation on reporting of communicable diseases and agents posing a threat to public health (No.221/2012, last amended in 2023), sets out procedures and responsibilities for reporting on communicable diseases, chemical agents, radiation and unusual and unexpected serious events that may pose a threat to public health or across borders, as well as antibiotic use and vaccinations. It describes the roles, instructions and obligations of the Chief Epidemiologist, healthcare professionals and entities (healthcare providers, laboratories, and other entities involved in diagnosing and managing communicable diseases) in regard to the list of diseases subject to registration and notifiable diseases, in which various AMR-related agents are listed. The regulation covers the information that is obliged to be disclosed when a suspected or identified case of diseases subject to registration or notifiable disease has to be reported. It also mentions the possibility of collecting additional information on a case if requested by the Chief Epidemiologist. While legislation explicitly identifies some AMR-pathogens subject to registration for surveillance, there is no specific legal framework dedicated solely to AMR surveillance. Broader surveillance of AMR in Iceland is primarily covered by a tacit obligation, supported by law, under the Chief Epidemiologist's role to ensure comprehensive monitoring.

Monitoring and reporting AMR in animals is under the responsibility of the Icelandic Food and Veterinary Authority, under the Regulation on the monitoring of antibiotic resistance in live animals, food, feed, fertiliser and seed products (No.1000/2018, last amended in 2022) and Regulation on the monitoring of zoonoses (diseases transmitted between humans and animals) and zoonotic agents (No.1048/2011). These regulations mandate that antibiotic susceptibility screenings should be conducted regularly for different animal species and pathogens associated with foodborne diseases. The testing targets the antibiotic susceptibility of *Salmonella spp.*, *Campylobacter jejuni and coli*, and *E. coli* bacteria.

The Medicinal Products Act (No.100/2020, last amended in 2024) defines the actors and their responsibilities in regard to antibiotics use and sales. Under the Act, the Directorate of Health shall operate and maintain the Prescription Medicines Register covering prescriptions and dispensing of medicinal products and containing data mandatorily recorded from pharmacy licence holders. This database should also support veterinary medicinal product prescriptions. As all antibiotics for human or veterinary uses require a prescription, all antibiotic prescriptions for both humans and animals are registered in this database. It serves as the basis for the Chief Epidemiologist to maintain a register on antimicrobial consumption data in the Icelandic population (mandates by the Regulation on reporting of communicable diseases and agents posing a threat to public health (No.221/2012, last amended in 2023)). The same Act requires wholesale authorisation holders, who sell medicinal products to pharmacies, healthcare institutions, physicians, dentists and veterinarians, to record sales information electronically and report it to IMA.

In 2017, a working group released a report (*in Icelandic*) outlining key actions against the spread of antibiotic resistance. By 2019, recommendations from the report were officially adopted as the national policy for AMR surveillance in Iceland by the Ministers. In July 2024, a National Action Plan on Antimicrobial Resistance for the period 2025-2029 was published by the Ministry of Health, aiming to enhance surveillance efforts and improve education and awareness on AMR (public, producers, veterinarians, etc.). The Action Plan has been developed in a One Health perspective, in collaboration with the Ministry of Food, Fisheries and Agriculture, and the Ministry of the Environment, Energy, and Climate, and focuses on six main actions:

1. Promote targeted and prudent use of antibiotics in humans and animals
2. Limit the spread of antibiotic resistance through information dissemination, education, and prevention
3. Improve knowledge of antibiotic resistance through surveillance and scientific research
4. Limit the spread of antibiotic resistance through interventions including wastewater treatment (*cf. Chemical threats – Water quality surveillance*)
5. Increase participation in international cooperation on actions against antibiotic resistance
6. Ensure coordination and management of actions against antibiotic resistance in the future to come

To facilitate effective communication and progress, a formal multisectoral committee will be established, holding regular meetings and guided by a cooperation agreement. Additionally, there will be a commitment to produce an annual report outlining the progress made throughout the year in relation to this Action Plan.

Additionally, the Icelandic Food and Veterinary Authority has defined its own annual national monitoring plan for 2024-2025 where a priority has been set on the correct use of antibiotics with specific monitoring at establishments that receive antibiotics from specific antibiotics categories/groups.

III. Chemical threats

In Iceland, chemical threats are generally related to industrial activities, environmental pollution and natural hazards. Monitoring takes place around the control of production and use of chemicals, and the environmental surveillance of air and water pollution.

a. Key actors and stakeholder networks

The **Ministry of Environment, Energy and Climate** *(Umhverfis-, orku- og loftslagsráðuneytið – previously: Ministry of Environment and Natural Resources)* is the legal entity responsible for overseeing environmental surveillance in Iceland. It sets policies and legal frameworks related to chemical safety, and human and environmental protection, ensuring Iceland's regulations align with European standards. Its role is also to validate plans (general, monitoring and action plans) related to environmental surveillance, including chemicals monitoring, in Iceland. The Ministry also sets regulations in regard to the registration, evaluation, authorisation and restrictions, classification and labelling of chemicals and toxic substance safety.

The **Icelandic Environment and Energy Agency** (IEEA – *Umhverfis- og orkustofnun, previously Icelandic Environmental Agency)*[26], under the Ministry of Environment, Energy and Climate, is the authority responsible for enforcing European and national regulations regarding environmental surveillance and pollution prevention in Iceland. As an expert agency, it is called upon to participate and draw up monitoring and action plans, at the request of the ministry concerned, and their implementation for guaranteeing environment quality. It has mainly a role of guidance for unified information across all actors involved in chemical surveillance. It coordinates the monitoring and ensures that it is carried out according to a uniform methodology which ensures both scientific quality and comparability of results. The IEEA coordinates the local health committees and municipalities, and actions in the event of acute or serious pollution accidents or other hazards of a similar nature.

For the current report, the key units or departments of the IEEA include:

- The **Chemicals Unit** advises the Ministry and supervises the implementation of regulations concerning the use of chemicals in Iceland. It actively monitors the placing on the market of chemicals in Iceland (including restrictions) and supervises the classification, labelling and packaging of chemicals marketed in Iceland. The Unit also has the responsibility to inform the public of the risks of chemical use on health and on the environment[27].
- The **Department for Air Quality Surveillance** and local health committees are responsible for monitoring and coordinating measurements of environmental quality about air quality and pollutants. It supervises municipalities and coordinates with them the implementation of monitoring and action plans and can ask for stricter requirements. Local health committees in each municipality are responsible for taking appropriate measures to ensure the implementation of the appropriate measures or

[26] *The Icelandic Environment and Energy Agency commenced operations on 1st January 2025. The Environment and Energy Agency takes over the operations of the National Energy Authority and parts of the Environment Agency. In addition, Nature Conservation Agency of Iceland was established.*

[27] *Complementary tasks are done by 2 distinct units: The Permits and Reviews Unit is responsible for issuing operating licences for chemical industries and waste management; and the Inspections Unit handles regular inspections of those holding operating licences issued by the Permits and Reviews Unit. Licences for operations are either delivered by the Permits and Reviews Unit of IEEA or the local Health committees depending on the type of operation concerned.*

plans for the purpose of achieving defined environmental goals. The Air Quality Surveillance Department must provide the public with information about air pollution and its risks.

- The **Unit for Ocean and Water** is responsible for administration in the field of water protection in Iceland, which includes coordinating monitoring, management and implementation of a national River Basin Management Plan. It sets environmental objectives for Icelandic water bodies and registers information on water quality assessment. The Department organises, supervises and ensures that monitoring and assessment studies of water pollution are carried out. The Unit ensures the dissemination of information to the public on water quality and pollution.

The **Icelandic Meteorological Office** (IMO – *Veðurstofa Íslands*) is a governmental institution under the Ministry of the Environment and Natural Resources, which primarily focuses on monitoring and forecasting weather and natural hazards. It plays a supportive role to the IEEA in real-time environmental monitoring, particularly by operating additional surveillance systems to support broader quality assessments and environmental monitoring efforts (e.g. hydrological measurements, an atmospheric monitoring program for volcanic gases, etc.). The IMO has an expert consultative role in the development and validation of monitoring plans and action plans. Additionally, they support emergency response efforts by providing weather forecasts and atmospheric data.

The **Centre for Health Security and Communicable Disease Control**, at the Directorate of Health led by the Chief Epidemiologist, is responsible for the organisation, coordination and supervision of communicable disease control and prevention throughout Iceland. The Chief Epidemiologist also has the authority and the legal basis to collect information of diseases caused by toxic chemicals and radiation or by unusual and expected events which may pose threats to public health. All related information is stored in the Communicable Diseases Register.

Local Health committees assess the local impact of pollution on public and environmental health. They are responsible for submitting information on the results of quality and pollution control and measurements to the IEEA. They supervise local monitoring and the management of surveillance and data collection systems. They participate, assisted by the IEEA, in the preparation of local action plans (short and long-term) and prevention measures to address pollution issues, and enforce regulation at the community/municipality level. They are the local authorities that must take measures to reduce pollution and respect the defined environmental limits (e.g. restrict traffic or activities in areas for a short period of time if pollution significantly exceeds applicable environmental limits due to unforeseen incidents or if there is discomfort caused by pollutants). Health committees are responsible for the local dissemination of information on pollution issues and risks to public and environmental health. They issue operational permits (for healthcare centres, hospitals and medical institutions, wastewater treatment and sludge treatment), in which they can impose stricter requirements or require additional monitoring (substance(s), criteria, frequency, locations, etc.) that are deemed necessary.

Industrial and energy actors (private sector) are the key stakeholders in emission control. They are required to comply with chemical and environmental regulations through permits. They are responsible for measuring or having the pollution factors measured in accordance to regulations and permits. They must submit to regular reporting and inspections.

Municipalities are a stakeholder when it comes to assessing pressure on water and where needed to develop (with the IEEA) actions to reduce pressure on water in the River Basin Management Plan. They are responsible for wastewater treatment, and therefore responsible for ensuring that discharges are in accordance with national regulation and the conditions in the operating license. They work in collaboration with health committees to implement actions aimed at avoiding or correcting potential environmental risks caused by chemical threats.

b. Digital infrastructures and systems

Water quality surveillance

i. Data sources

Water surveillance in Iceland is framed by European directives and aims to monitor chemicals and pollutants in surface waters and groundwaters to assess the ecological and chemical status of the different national water bodies.

Iceland has introduced a River Basin Management Plan, eligible from 2022 to 2027, for the overall protection of water bodies in Iceland, accompanied by a Monitoring plan in which all monitoring sites in Iceland are defined in detail. Monitoring sites include natural water bodies and those under human-induced stress (e.g., pressures due to the discharge of wastewater, pressure from urban areas, commercial activities, industry or farming and agriculture).

As no groundwater body is planned to be monitored, according to the Water Plan 2022-2027, the following section will focus on surface water surveillance[28].

Surface water quality monitoring

Surface water monitoring is mostly carried out by a surveillance monitoring. This monitoring focuses on ecological quality factors (biological, physicochemical and hydro morphological characteristics of the water body)[29] and chemical conditions. The chemical condition of a water body is assessed by the measurement of specific pollutant concentrations, classified as '*priority substances'*. The specific priority substances being monitored in surface water are defined by regulation and include 45 substances, including metals, pesticides and biocides, industrial chemicals and halogenated organic compounds. Priority substances are monitored in those Icelandic water bodies that have been identified as being at risk of exposure and are measured by their concentration in either water, sediment, or biota.

The information collected, accompanying each sample, includes: the date of the sampling and the sampling methods, the quality factors intended to be measured, its value and unit of measurement, the matrix in which the measurement was taken (i.e. surface water, sediment, etc.), the measurement purpose, the GPS coordinates and the site name.

The assessment of the different ecological quality factors allows the classification of the water bodies ecological condition (as *'high', 'good'* or '*bad*') and its chemical status (as either '*good'* or '*poor*').

Seven networks[30] are dedicated to surveillance monitoring, each of the monitoring networks intended to provide a specific type of information with its category of monitoring and its objectives. The complete list of water bodies in Iceland and their assigned network(s) is

[28] *The status classification of ground water is based on physico-chemical factors (e.g., oxygen content, pH, conductivity, nitrate and ammonium) and its quantitative status. The appendix of Regulation on Protection against ground water pollution (No.797/1999) lists the substances and chemical compounds that must be monitored in ground water in Iceland.*

[29] *These factors are used for the ecological state classification of surface water bodies. For each type of surface water body, the specific biological, physico-chemical and hydromorphological conditions are compared to the values of 'very good' ecological conditions (natural and unpolluted conditions). These three factors together allow the assessment of the 'health' of aquatic ecosystems. The frequency of monitoring these parameters varies due to conditions on site and possible pressures. The aim of sampling is to reflect potential changes due to pressures.*

[30] *All local health committees have water bodies within their geographical limits that are included in at least one surveillance monitoring network, and could be part of multiple network. Local health committees and the Marine and Freshwater Research Institute are responsible to conduct part of the summary monitoring.*

available in the Monitoring plan of the River Basin Management Plan 2022-2027 and as a map in *Vatnavefsjá*, which is a geographic information system for water management.

The information collected listed above and the results of monitoring are submitted to the IEEA via a data portal for water monitoring. If the submission concerns a single measurement for a water body, it can be directly entered manually in the data portal. If the submission concerns all sets of data collected for a water body, they are uploaded on the data portal via an Excel sheet.

Additional monitoring of surface water in Iceland has been established and concerns: EU watchlist substances and wastewater surveillance.

EU watchlist substances

Substances on this watchlist are considered '*harmful to the environment but information about them is not sufficient to assess the risk'*. This includes pharmaceutical residues (hormones, antibiotics, anti-inflammatory drugs, antifungals, antidepressants/antipsychotics), fungicides, insecticides and pesticides. These substances must be monitored at selected and typical monitoring points over a two-year period. In Iceland, the sampling is conducted once per year at three to five sampling points. The list of chemicals is defined and updated every two years by the EU on Member State (MS) collective results and expert groups' input (the last update was in 2025). This list also supports Iceland in the assessment of the status of its water bodies.

Wastewater surveillance

Wastewater has been identified as one of the major stressors applied to Icelandic water and is required to be monitored. As for water quality surveillance, samples are collected by the local health committee or sewage workers (if the operator is entrusted with this task in their operating licence) and information is submitted to the IEEA through the data portal for water quality monitoring.

Wastewater surveillance in Iceland is based on the measurement of the biochemical oxygen demand (BOD_5) and the chemical oxygen demand (COD), which are complementary measurements for the evaluation of wastewater treatment effectiveness and overall pollution of the water. Particulate matter in suspension is also measured to assess the level of pollution or insufficient treatment of wastewater, as these particles can harbour pathogens, organic pollutants (pharmaceuticals and pesticides) and chemical pollutants. Additional data collected include: the name of the urban wastewater facility and its GPS coordinates. The data portal is ready for the submission of wastewater data but those data are currently scarce since very few facilities are measuring wastewater.

Priority substances are also subject to measurement in wastewater depending on the circumstances (discharge of these substances is not permitted or subject to a work permit). The annual minimum number of samples taken at a treatment plant is determined according to its classification in terms of personal unit (PE)[31] and the sensitivity of the site[32].

[31] *Personal unit (PE) is the amount of organic substances and others that corresponds to what one person is normally considered to release in a 24-hour period. One PE of organic matter is the amount of matter in sewage that can be broken down biologically with 60g of oxygen per day measured by a BOD_5.*

[32] *Frequency of sample per measurement factors (PE, BOD_5,COD, particulate matter, etc.) is available in the Guidelines on monitoring measurements and monitoring for sewers of the Icelandic Environmental Agency.*

Information related to chemical surveillance in Icelandic water, including wastewater, is stored at a national level by the IEEA. No secure cloud for data storage of chemical surveillance in water is in place.

ii. Data linkage and sharing

Annual monitoring results in Iceland for wastewater are submitted to the European Environment Agency (EEA), although only results from agglomerations that discharge more than 2,000 personal units are shared.

iii. Standards and data quality

The methods used to control the quality factors of surface water bodies comply with international standards and include the use of Icelandic and foreign standards, which makes it possible to obtain comparable data of comparable scientific quality. The choice of standards took account of the quality elements and assessment elements used to determine the status of a water body.

The information submitted via the data portal follows a template page (for single measurement submission). In case the submission does not satisfy the requirement of the IEEA, it can require completing or repeating the submission of information.

Chemical substances monitored in water are listed and named following the Chemical Abstracts Service Registry Number[33].

iv. Reports

Data on general water quality measurements or related to a specific water body are available in the Water Quality monitoring's API. Some results of the overall surveillance and by sites are publicly available on the IEEA' website. Future reports will appear and be accessible in the same location.

Every two years, in collaboration with health authorities, municipalities and sewer operators, the IEEA compiles information on the status of wastewater in Iceland in reports made available on their website. Results are displayed only for agglomerations that release more than 2,000 PE (29 defined densely populated areas, covering 89% of the Icelandic population). These reports address guidelines and plans that need to be put in place for each wastewater surveillance point.

The IEEA has the willingness to start a mapping exercise of the chemical surveillance in water to display in one platform all the information related to pollution in water (infrastructure nearby, locations of outlets, treatment plants, type of pollution, type of chemical, etc.).

v. Threat indicators

For summary monitoring, each indicator, either ecological or chemical, is compared to an environmental quality requirement (threshold)[34]. The assessment of the different indicators classifies the water body's ecological and chemical conditions. These classifications are

[33] *Unique identifier number assigned by the Chemical Abstracts Service in the United States of America to every chemical substance. CAS Registry - Chemical Abstracts Service.*

[34] *The environmental quality requirement (UGK – Umhverfisgæðakröfur) is defined as the maximum permissible concentration of a specific pollutant or group of pollutants in water, sediments or the ecosystem may not be exceeded and are set to protect human health and the environment.*

combined to determine the overall condition of the water body, which may necessitate action to be put in place. The assessment and validation of any potential threats, including chemical ones, in Icelandic waters, remain the responsibility of experts.

For chemical threats, an annual average concentration for each priority pollutant is calculated when detected. If the average concentration in a water body exceeds the environmental quality requirement measure (List III in Regulation No.796/1999 on prevention of water pollution, last amended in 2015), analytical work on the sources of the substance is put in place (operational or investigative monitoring), to be able to make decisions about the next steps to reverse the conditions of the water body (identification of one or multiple sources of contamination)[35]. This investigation is carried out by the IEEA Unit of Ocean and Water, in cooperation with local health committees and may include the participation of other actors (e.g., the consultation of the Chemicals Unit of IEEA or the Poison Information Centre for the Safety Data sheets).

Currently, no specific substances have been defined as '*other pollutants*' for Iceland[36], either for individual water bodies or specific areas. Their monitoring is therefore not required. If such substances are identified in the future, the need for monitoring will be reassessed, with a minimum requirement of four monitoring events per year.

Operational monitoring, conducted by the IEEA or local authorities aims to collect specific information to assess the impact of human-induced stress on the surface water. The operational monitoring intends to establish and confirm the state classification of the water body and allows closer monitoring to reveal possible changes in the status of surface water. This monitoring is also used to evaluate the effectiveness of actions taken in a specific water body. This type of monitoring is conducted in water bodies at risk of not achieving 'good' status classification, as identified by surveillance monitoring or other evidence of poor chemical status. Only the most sensitive quality factors (origin of the stress identified by early results of the summary overview) of the specific water body are monitored.

Investigative monitoring, conducted by the relevant competent authority and/or through pollution permits, is carried out if the reason for exceeding the environmental quality requirement tolerance limit is unknown (the surveillance monitoring has confirmed that the water body's quality objectives are unlikely to be achieved, and operational monitoring has not been established to determine the impact of pollution). Investigative monitoring focuses on only a few qualitative aspects that are specifics and considered relevant for this type of water body and its assessment with environmental objectives. This monitoring is usually applied when pollution accidents occur. The factors that provide information on the scope and impact of the accidents must be studied and can become the basis for deciding on the necessary measures to reduce the frequency and impact of such accidents.

Three monitoring networks for surface water are dedicated to operational monitoring and one to investigative monitoring (visible on *Vatnavefsjá*). Operational monitoring is recommended, by the IEEA, to be more frequently carried out than surveillance monitoring (except for priority substances for which the frequency of monitoring is identical). The frequency of investigative monitoring varies and depends on what the investigative monitoring is intended to reveal. Their

[35] *In case of the ecological condition of a water body is temporarily deteriorated due to natural causes or uncontrollable external events, are not considered as a violation of the environmental requirements goals. In these circumstances, practical measures should be taken as long as the condition of the water body does not deteriorate.*

[36] *Based on the River Basin Management Plan, they are defined as polluting substances (other than priority substances) which have been introduced in significant quantities from polluting activities into water bodies. It concerns substances like heavy metals, chemical compounds and pollution caused by one priority substance that have been discharged into a specific body of water. Viruses and bacteria can also be considered in this list.*

submission of data depends on the frequency established concerning the chemical threat. Results of the investigation analysis are submitted to the IEEA data portal for water monitoring and reported by the agency on the abovementioned outputs (reports and API).

If a water body has failed to reach '*good'* status those responsible for the deterioration will have to put forth actions to reduce pressure and ensure that the water body reaches good status.

The results of operational and investigative monitoring are submitted to the IEEA via a data portal for water monitoring, under the same conditions as for the surveillance monitoring.

Accompanying the River Basin Management Plan is the Programme of Measures (PoM) which is a key tool to implement policies and measures that are necessary to ensure or achieve good status of water. The implementation of the measures is distributed among different parties (local authorities, health authorities, water committees, industry representatives, polluting actor(s) identified, etc.). Each action has its responsible person who must ensure its execution as described in the Programme of Measures. According to the law on Water Management, the monitoring, measures and actions set out in the Programme of Measures must be completed within the six-year duration of the plan for water bodies to achieve their environmental goals[37].

In wastewater, an assessment of effectiveness indicators is done by comparison to a maximum concentration (threshold in mg/L indicating enough treatment) or a minimum reduction of substances in wastewater (percentage of minimum pollution reduction before wastewater is discharged into the receiver). If the results of chemical measurements are above the emission limit, the licensed operator of the wastewater must notify the health committee and follow up with chemical measurements.

The Programme of Measures includes measures addressing wastewater-related issues. Some actions have already been completed, and an overview of completed and planned actions is available in the IEEA's biennial report (last update 2022).

[37] *Deadlines for achieving environmental goals can be granted twice, six years at the time.*

Industrial chemical products surveillance

i. Data sources

Chemical surveillance in Iceland also includes market surveillance and authorisations. The IEEA is responsible for monitoring the production, import, treatment, and marketing of all chemical substances in Iceland.

Manufacturers or importers are required to submit specific information about the chemicals they handle to the Poison Information Centre (*cf. Poison Information Centre chapter*) using Safety Data Sheets (following recommendations of information compilation of the European Chemical Agency (ECHA)). The IEEA collects information on chemicals produced or imported through operation permits, market surveillance, etc. However, the Poison Information Centre reports yearly to the IEEA on poisoning threats for surveillance purposes and to be used for prevention measures.

Chemical inspections and reporting are either done by local health committees or the IEEA, depending on the size of the suppliers, the issuer of their operating licence and the type of inspection. Local health committees must report to the agency about non-compliances or suspected non-compliances discovered during their inspections. If safety measures need to be implemented, the IEEA is responsible for coordinating this implementation (i.e. research for the next chain up, small suppliers are usually linked to a larger national/regional chain). The agency has its own Inspection Unit, specialised in aluminium smelters and *'large'* industries with operating licences issued by the Agency's Permits and Reviews Unit. These industries are inspected annually and subjected to a collection of random samples on sites. After each inspection, a report is drawn stating the results and published on the IEEA's website (inspection reports, quarterly reports, environmental monitoring, green and emissions accounting, measurement and monitoring reports). For controls carried out by the Chemicals Unit, the results of the inspection and what measures have been taken by the IEEA can be found on a research platform.

Local research centres are responsible for the monitoring and measuring of chemicals in the vegetation and the environment, collecting data not provided by the licensed contractor.

All information is stored at a national level. No secure cloud for data storage is in place.

ii. Data linkage and sharing

As part of the EEA, the agency works on implementing EEA legislation on chemicals. The Chemicals Unit is also involved in Nordic and European cooperation through the ECHA. Experts in the Chemicals Unit regularly review the reports submitted to the Safety Gate notification system of the European Commission. This system publishes notifications about products on the market in EEA states that do not comply with the requirements of national legislation for human and/or environmental safety. Following certain EU Chemical Regulations (such as Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), Classification, Labelling, and Packaging (CLP) or Biocidal Products Regulation (BPR)), data on official controls is reported to the European Commission every five years.
Data with outcomes from specific enforcement projects has been shared with Nordic collaborations through presentations and discussion of the Nordic Enforcement Group, including topics as rate of non-compliance, types of non-compliances found and measures imposed.

iii. Reports

Any type of reports, decisions and plans issued by the IEEA's Chemicals Unit team are published on the IEEA's website.

The Chemicals Unit has made plans for a database compiling every inspection report (including those proceeded by local authorities). A mapping exercise for the intended structure of the database system has already been done.

iv. Threat indicators

In case of a chemical threat or spillage, the IEEA's Chemicals Unit may be engaged depending on the initial response, the actions taken by the first responders, and the severity of the situation assessed by the local health committee. Other teams at the IEEA can be involved depending on the context of the chemical threat:

- For an accident at sea, the Ocean team is mobilised and responsible for the coordination of the response (e.g., mobilisation of other agencies). In that case, the first responder is the Coast Guard.
- For an accident on land, local health committees are responsible for coordinating the effort, requesting the engagement of the Chemical team. In that situation, the first responder is the Fire Department.

In case of consequences of a chemical threat, the IEEA's Chemicals Unit is responsible for sharing information about public health hazards. However, no clear threshold is defined for reporting such a threat. In this regard, a formalised process of reviewing the preparedness plan was carried out and finalised in autumn 2024, to better define responsibilities in case of chemical threats. Its implementation is currently on hold and is expected to start in autumn 2025.

Air quality surveillance

i. Data sources

For air quality monitoring in Iceland, the IEEA and local health committees conduct chemical measurements to detect any pollution or contamination. Air quality and composition are measured and identified by 40 operating monitoring stations (mostly in the capital area). Data from the stations are automatically collected by a comprehensive air quality information system *Airviro*[38]. *Airviro* is an integrated system used to keep track of all air pollution measurements in the form of time series. The system provides tools for presentation and advanced statistics enable to build predictive and distribution models (e.g., air distribution models for air pollutants, dispersion models in urban areas, general air quality models, etc.).

The main air pollutants measured in Iceland are: *Sulfur dioxide* (SO_2), *Hydrogen sulphide* (H_2S), *Carbon dioxide* (CO), *Nitrogen oxides* (NO_2 and NO), *ozone* (O_3) and *particulate matter* (PM_{10}, $PM_{2.5}$ and PM_1)[39]. As weather conditions (temperature, wind, humidity, precipitation or seasonality) can be highly influential on the measure of concentration of an air pollutant, the *Airviro* system is enhanced with national weather forecasts data provided by the IMO.

Daily, *Airviro* streams air quality data in a near real-time manner. A dashboard (map viewer), open to the public, serves as support to present the current data measured at the various stations in place. For each station, the platform presents the air quality indicators measured over the last 48 hours and can be requested for an earlier date or period.

Additionally, to the stationary monitors, the IEEA can deploy mobile measuring units for close monitoring of specific events (e.g., volcanic eruption). Data collected by these monitoring stations are also displayed on the dashboard and available for download[40].

Airviro acts as a national comprehensive database for all air quality monitoring data. All data in *Airviro* is stored on a secure cloud.

ii. Data linkage and sharing

Iceland reports all data of its stationary monitors (not including the mobile units' measurements) to the EEA via the European Environment Information and Observation Network (Eionet) workspace[41]. This workspace gathers and develops data to advise policymakers about Europe's environment. Reported data can include daily, hourly and annual averages of air pollutants, the number of instances in which a specified threshold is exceeded and the identified source(s) of air pollution.

The IEEA delivers reports on the release of air pollutants in Iceland to the United Nations Convention on Air Pollution (the Convention on Long-range Transboundary Air Pollution). The Convention requires the monitoring and reporting of heavy metals and persistent organic

[38] *Airviro is a monitoring system developed by the Swedish Meteorological and Hydrological Institute (SMHI). It is implemented in Iceland since 2017.*

[39] *Not all air pollutants are measured at each site.*

[40] *This is usually not an equipment eligible for the Air Quality Directive but information collected from various sensors.*

[41] *Unverified primary data is uploaded every hour in the E2a dataflow, verified data is reported yearly in the E1a dataflow, following EEA terms.*

pollutants in precipitations and particulate matter samples. The results of measurements are submitted and stored in the European Monitoring and Evaluation Programme (EMEP)[42].

iii. Standards and data quality

The main air pollutants are quantified by their concentration in the air (µg/m^3). Depending on the frequency of measurements required for a main air pollutant (from the daily hourly average to the annual average)[43], the frequency of data collection from monitoring stations varies from 10 minutes to 1 hour.

All operating monitor stations are calibrated once a year (not including the mobile units).

Regarding the API, the standards employed are aligned with those utilized by *OpenAQ*. *OpenAQ* is an environmental technological non-profit agency that aggregates and harmonises air quality data from across the globe onto an open-source, open-access data platform. A collaboration between the IEEA and *OpenAQ* was already in place, and close contact was put in place before the implementation of the API for an easy transfer between the two entities.

Data on general measurements or related to a specific station are available in the air quality monitoring's API (with the exception of those from mobile units), in JSON or CSV format.

iv. Reports

All data collected are reported in an annual national report on air quality trends in Iceland (last update 2021). This report is accompanied by a summary report focusing on environmental indicators for health protection limits. The summary report is expected to be reviewed regularly during the year. All national reports are publicly available on the IEEA website.

v. Threat indicators

Threat detection, concerning air quality, is both event-driven and threshold-based. For the main pollutants that serve as environmental indicators, the measured concentration is compared to a health protection limit. For some pollutants (PM_{10}, NO_2, SO_2 and H_2S), a permissible number of times above the health protection limit has been defined[44].

If the concentration of any air pollutant exceeds the defined limit, the monitoring sensor triggers notifications to the responsible authorities (health committees managing measuring stations, operators of air quality monitoring stations, or the IEEA). Experts are always involved in assessing and validating the potential threat. Any exceedance is reported to the IEEA, involving an investigation into its underlying cause or source (such as traffic of cars, ships, and other vehicles), heavy industry, natural phenomena (hot springs or volcanic eruptions), or geothermal power plants. Subsequently, targeted follow-up measures are initiated to reduce the likelihood of similar incidents recurring.

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[42] *The team in charge of water surveillance within the Icelandic Environmental Agency is also involved in projects related to the Convention on Long-range Transboundary Air Pollution.*

[43] *The required time of measurement and health protection limits per main air pollutants, according to European and Icelandic regulations, are reported in the Air Quality Plan.*

[44] *It refers to the allowable frequency within a specified period that pollutant concentrations may surpass the established threshold without being considered a violation of the standards. This provides flexibility for occasional spikes in pollutant levels due to specific circumstances, such as unusual weather conditions or temporary emissions, while ensuring overall air quality remains within acceptable limits. Authorised exceedances are indicated in European and Icelandic regulations. If there are reasons for that due to natural causes, the times may be deducted from the total number of times that exceed the limit, where it is considered that it is not possible to have countermeasures to reduce such pollution.*

The local health committees work in close collaboration with the IEEA to address any detected threats related to air quality. If there is a risk of exceeding health limits, short-term measures to improve outdoor air have been defined (per type of pollutants) and their implementation is under the responsibility of health committees (e.g., restriction or ban of vehicle traffic, speed limits, information and guidance to professionals and the general population, encouragement for increased use of public transport, etc.)[45]. Simultaneously, the IEEA, in coordination with epidemiologists, is responsible for issuing guidelines to mitigate air pollution, informing the public about potential health effects, and assessing whether evacuation of the affected area is necessary.

In the case of extreme values, the Department of Civil Defence in the national police is involved in managing the threat and supporting communication to the public through the media regarding restrictions and guidelines. This only applies in very high concentrations, which can occur, for example, when a volcanic eruption is active. General recommendations and guidelines regarding air pollution are available on the IEEA's website. Preparedness tables are available, linking EU regulatory thresholds and instructions for the general public. In addition, a guide of protective measures against air pollution from volcanic ashes has been published by a consultative group of The Chief Epidemiologist and The Department of Civil Protection.

vi. Medical countermeasures

In response to volcanic eruptions, national authorities are tracking the use of inhalers and respiratory medications, specifically in affected areas where respiratory distress is considered likely to be observed. This mechanism has been developed in collaboration with the Centre for Health Security and Communicable Disease Control, Directorate of Health and local authorities, and relies on existing monitoring systems. The mechanism is only in use during eruptions, and can be activated when pollution levels rise, allowing for the collection of weekly reports on respiratory-related issues. This monitoring provides detailed insights beyond diagnoses, offering a more comprehensive understanding of health impacts during such events.

[45] *Measures per pollutants and per risk are presented in the Air Quality Plan.*

c. Legislation and strategy

Chemical surveillance is globally supported by the Act on Hygiene and Pollution Prevention (No.7/1998, last amended in 2024). The Act establishes regulations to protect public health and the environment by preventing and mitigating pollution. It encompasses a wide set of areas that can be impacted by or result from pollution, such as water and air quality, hazardous substances and industrial emissions. The Act promotes sustainable practices, requires environmental monitoring and enforces permits and inspections for potentially polluting activities, ensuring compliance with international environmental objectives.

The CBRNe National Plan (2020) categorises chemical threats based on their effects and methods of exposure. Chemical agents are classified as irritants, incapacitating agents, and lethal agents, with further categorization by their entry pathways, such as respiratory agents, skin-absorbing agents, and blood toxins. The document emphasises incident response strategies, including risk assessment, containment, and medical intervention. It details specific chemical hazards, such as mustard gas, sarin, cyanide, and chlorine, along with their potential impact on public health. Past chemical incidents in Iceland, including chlorine gas leaks and volcanic gas emissions, are referenced to highlight real-world risks and emergency preparedness measures. Additionally, the plan outlines preventive measures, including hazardous material labelling, safety protocols, and interagency cooperation to enhance preparedness and response effectiveness.

The Regulation on infection prevention control measures (No.817/2012, last amended in 2024), complementing the Act on Health Security and Communicable Diseases (No.19/1997, last amended in 2024), details protocols and measures in place in Iceland for managing a case of disease subject to registration. It specifies the roles and responsibilities of the Landspítali – University Hospital and primary health care for the diagnosis, isolation and treatment of patients due to the consequences of toxic substances. Additionally, the regulation briefly addresses the requirement of a safety stock of medicines and other medical equipment (including PPE) of the Chief Epidemiologist and defines Iceland's key points of entry for infection control.

Water quality surveillance

The Water Management Act (No.36/2011, last amended in 2024) governs the sustainable use and protection of Iceland's water resources, providing a clear framework for the country's water protection actions. Its primary goal is to ensure the preservation of water quality and ecosystems under the EU Water Framework Directive (Directive No.60/2000) and requires the monitoring of EU priority substances and watchlist components (Directive No.105/2008). This Act requests the establishment of a Monitoring Plan and a Programme of Measures for each type of surface water, groundwater and coastal water. According to the Water Management Act:

- The Monitoring plan[46] prescribes analysis, mapping and monitoring of all water in Iceland and the reference conditions for each type of water body[47] and it is used to

[46] *The Monitoring plan is a comprehensive plan for monitoring the different types of water bodies in Iceland, including plans for improvement. It provides a consistent and comparable methodology for water monitoring.*

[47] *Specific plans have been also established for defined protected and sensitive areas (i.e., water bodies where drinking water is abstracted, areas designated as habitat protection or species, recreational waters, waters sensitive to nutrients, etc.).*

provide an overall view of the state of water bodies. The legislation prescribes the regular revision of the Monitoring Plan at least every six years.

- The Programme of Measures specifies the measures to be taken to achieve environmental goals for the different water bodies. A part of the Action Plan is the revision of the existing polluting permits, also delivered for private operators.

The Icelandic Regulation on the Management of Water Affairs (No.935/2011) implements the Icelandic Water Management Act. It outlines the procedures for developing and implementing water management plans, focusing on protecting and improving water quality and ecological status. The regulation mandates the classification, monitoring, and assessment of water bodies and establishes environmental objectives. It also emphasizes sustainable water use, addressing pollution control, and safeguarding aquatic ecosystems.

The Regulation on the classification of water bodies, their characteristics, pressure analysis and monitoring (No.535/2011, last amended in 2015) sets out further requirements for monitoring substances on the priority substances list. This regulation establishes the criteria for classifying Iceland's water bodies based on their ecological and chemical status (in alignment with the EU Water Framework Directive). It sets out methods for assessing the health of surface and groundwater, including the ecological, chemical, and physical parameters. The regulation aims to identify water bodies at risk of failing environmental objectives and supports the development of strategies to protect and improve water quality. It provides a framework for consistent water classification to guide sustainable management and conservation efforts.

Iceland has introduced a general River Basin Management plan, eligible from 2022 to 2027, accompanied by a Monitoring plan and a Programme of Measures requested by the legislation and described above. In the timeframe of this first Water plan, it is planned to monitor four coastal sea bodies, ten lake water bodies and nine river water bodies. No groundwater body or estuarine water body is expected to be monitored. The first Icelandic River Basin Management plan will prioritize the establishment of a water management system for comprehensive data collection and efficient monitoring. The aim is to simplify and facilitate data submission, national harmonization of the sampling method and analysis and allowing accessible information on water bodies to professionals and the general public through digital platforms. The River Basin Management plan also includes specific plans related to water protection at the municipality level.

A new Monitoring plan and Programme of Measures are expected for the next water cycle, covering the period of 2028-2033, building upon information gathered during the implementation and application of the Icelandic first water plan.

The Water Management Act complements other main regulations and legislations related to water protection, treatment and pollution, including:

- Regulation on protection against water pollution (No.796/1999)
- Regulation on protection against groundwater pollution (No.797/1999)
- Regulation on emissions from commercial operations and pollution control (No.550/2018)
- Regulation on protection against water pollution caused by nitrogen compounds from agriculture and other businesses (No.804/1999)
- Regulation on sludge treatment (No.799/1999)
- Act on prevention of marine pollution (No.32/1986)

Specifically targeting wastewater, the Regulation on wastewater facilities and wastewater (No.798/1999, last amended in 2009) establishes standards for the operation and maintenance of wastewater systems to prevent environmental harm and ensure public health. The Regulation includes requirements for the collection and treatment of wastewater to monitor wastewater management practices. The Act on the Development and Operation of wastewater facilities (No.9/2009, last amended in 2024) addresses the responsibilities of the municipalities as wastewater treatment providers and environmental protection by requiring the control of discharges and compliance with permits and standards. The Act also mentions the monitoring requirements for municipalities and operators of wastewater contaminants and supports coordination with the IEEA.

Associated with the AMR surveillance, only one screening for *ESBL/AmpC producing E.coli* has been performed in Icelandic surface waters (2019-2020), by the IEEA and the Food and Veterinary Agency, where 25 samples were taken in 11 sites (all samples were taken at locations associated with sewage outfalls). About 60% of the samples were positive for this resistant bacteria. Through the National Action Plan for AMR surveillance, Icelandic health authorities have the willingness to implement AMR surveillance through the Icelandic wastewater (*cf.* to actions 4.4 and 4.5 of the National Action Plan - *Treatment of wastewater for appropriate minimisation of the spread of certain antibiotic-resistant bacteria* and t*he development of guidelines on actions when resistant bacteria are detected in wastewater/environment*). Executive plans are for the moment in discussion within the EU-JAMRAI 2 Icelandic group, concerning the sites and the type of monitoring that should be put in place.

Industrial chemical products surveillance

Industrial chemical surveillance is under the Icelandic Chemicals Act (No.61/2013, last amended in 2024). This Act provides the legal framework for the management, use and control of chemicals to protect human health, animals and the environment. It aligns with EU regulations such as REACH and CLP. The Act outlines requirements for the registration, labelling, and safe handling of chemicals by companies, ensuring their proper assessment and monitoring by the IEEA and other administrative bodies. It also establishes rules for chemical import, production, and distribution while promoting transparency and public awareness about chemical safety. The responsibilities and roles of each party are described in the Act. However, discussions are ongoing to identify and further define the responsibilities stated in the Act of the different parties.

The IEEA issues operating licenses for polluting activities in accordance with the Act on Hygiene and Pollution Prevention (No.7/1998, last amended in 2024) and Regulation on emissions from commercial operations and pollution control (No.550/2018, last amended in 2022).

Air quality surveillance

The Act on Hygiene and Pollution Prevention (No.7/1998, last amended in 2024) addresses air quality as part of its broader environmental and public health objectives. Together with the Regulation on Air Quality (No.787/1999, last amended in 2013), they set the requirements for protecting, monitoring and reporting air quality in Iceland (amended in 2013 to align with the

European Directive on Air Quality and cleaner air in Europe (No.50/2008)[48]). They establish responsibilities for coordination and monitoring of air quality, setting pollution permissible limits, and implementing action plans in cases of non-compliance. They require a general plan for air quality, issued for 12 years at a time, which aims to ensure high air quality in all of Iceland, and action plans to reduce pollution. Additionally, they require specific plans tailored to the characteristics of air quality of municipalities to be developed.

The Icelandic Air Quality Plan, in place from 2018 to 2029, outlines strategies to maintain or improve air quality. The Air Quality Plan establishes objectives and actions to mitigate air pollution in Iceland, specifying the responsible parties for implementing each measure. Key measures include the regulation of emissions from transport and industry enhancing air quality monitoring and the surveillance of main pollutants in Iceland along with their sources.

Three additional Icelandic regulations, Regulation on sulphur dioxide, nitrogen dioxide and nitrogen oxides, benzene, carbon monoxide, particulate matter and lead in the atmosphere, the concentration of ozone at the earth's surface and information to the public (No.920/2016), Regulation on the concentration of hydrogen sulphide in the atmosphere (No.514/2010, last amended in 2014) and Regulation of arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in the atmosphere (No.410/2008), form a comprehensive framework for controlling air pollution in Iceland. They provide monitoring guidelines and set the limits (and warning limits) of air pollutants, for preventing or reducing adverse effects on human health and the environment.

Icelandic regulations align with the limits and recommendations established by European standards (EU Directives No.50/2008 and No.107/2004)[49].

[48] *Additionally to the European Directive relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (No.107/2004).*

[49] *At the exception of the Regulation on the concentration of hydrogen sulphide in the atmosphere, as no European limit has been defined. Iceland decided to set its own limit.*

IV. Biological and chemical threats / Poison Information Centre

a. Key actors and stakeholder networks

The **Ministry of Health** *(Heilbrigðisráðuneytið)* is responsible for the administration and policy-making in the field of health, including the enactment of laws and regulations. The Ministry of Health supervises the national efforts in disease control and health security questions including patient rights, health insurance, laboratory licensing and specific assignments, national public health affairs and healthcare institutions. In regards to biological and chemical threats, it decides, on the advice of the National Committee on Communicable Diseases, which diseases caused by toxic chemicals, additional to the communicable diseases (*cf. Pathogens with high pandemic potential chapter*), shall be notifiable, and which must be registered.

Landspítali – University hospital is the national university hospital of Iceland and the leading hospital in the country. It is funded by the Ministry of Health and supervised by the Directorate of Health. Landspítali – University hospital hosts the Poison Information Centre, under the Department of Pharmacology and Toxicology.

The Poison Information Centre (*Eitrunarmiðstöð*) is the nationally appointed body in relation to the submission of information for the purpose of emergency health response related to chemical threats. It is a specialized service in Iceland that provides information and assistance related to poisoning incidents. Operated as part of Landspítali – University Hospital, it offers 24/7 support to healthcare professionals and the public, and records incidents due to poisoning. The Poison Information Centre responds to inquiries about toxic substances and guides diagnosis, treatment, and prevention of poison-related emergencies. Importers, manufacturers, and other entities responsible for marketing hazardous substances or mixtures classified as dangerous are required to notify the Poison Information Centre about their chemical composition and effects, following its specified procedures. The Poison Information Centre collaborates closely with the IEEA, providing data on poisoning cases to help the agency inform the public about the risks associated with chemical use.

b. Digital infrastructures and systems

i. Data sources

All information relating to poisoning threat is collected in a national system managed through a 24/7 hotline operated by the Poison Information Centre. Through this hotline, people can receive advice on how to respond to poisonings, information on toxic substances, and recommendations for necessary actions (such as referral to a healthcare professional or emergency room). The hotline is staffed by a team of clinical pharmacists and physicians of the Emergency Department of the Landspítali – University Hospital.

This hotline is connected to other emergency numbers (the general Emergency Line of Iceland of the Department of Civil Protection and Emergency Management of the National Commissioner of the Icelandic Police, the number for the Emergency Department for Children and Adolescents and the number of the Information Centre for Primary Care).

Around 3000-3200 calls are received annually regarding poisoning inquiries from the general public or professionals (general practitioners, veterinarians, first responders, paramedics, etc.). Information is collected for each call and includes individual information of the patient (age, weight, social security number), name of the substance or medicine causing the threat, the occurrence and entry of the poisoning and the '*reason'* of poisoning.

All information is stored at the Poison Information Centre. No secure cloud for the information collected and analysed is in place or planned to be implemented.

Additionally, manufacturers or importers are required to submit specific information about the chemicals they handle to the Poison Information Centre using Safety Data Sheets (following recommendations of information compilation of the ECHA[50]). This information is submitted for the purpose of emergency health response regarding chemicals and stored by the Poison Information Centre.

ii. Data linkage and sharing

The Poison Information Centre reports yearly to the Centre for Official Statistics in Iceland (Statistics Iceland) on poisoning threats. These statistics are also shared with the IEEA for surveillance purposes and to be used for prevention measures.

The Poison Information Centre is part of the Nordic Association of Poison Centres[51], which aims to promote cooperation and exchange of experiences between poison centres for close collaboration with Member States part of this association.

iii. Standards and data quality

The Poison Information Centre has a list of necessary information that needs to be collected for each call received. All information collected is reviewed by the Head of the Poison Information Centre.

[50] *Guidance* on the *compilation of the Safety Data Sheets, including the detailed requested information, are available on the ECHA website.*

[51] *Including Denmark, Finland, Norway, Sweden, Lithuania, Estonia and Latvia. The organisation and actions of this association is not under any agreement, this collaboration between Member States is completely informal. Countries part of this membership are in regular close-contact and meet once a year.*

iv. Reports

Annual reports are prepared and publicly available on the Poison Information Centre webpage, with statistics on the total number of calls and threats addressed during the year.

v. Threat indicators

Through a phone call, the Poison Information Centre team provides recommendations for necessary actions based on the information received. However, in the situation where more expertise is required, the clinical toxicology specialist at the Poison Information Centre is involved in the assessment and validation of the recommended actions. Detailed instructions and operational plans are prepared and available for the toxicology experts and hospitals.

The Poison Information Centre can alert (by phone) the hospital of the entry of an individual with a risk of potential poisoning. At the same time and in anticipation of the patient's entry into the relevant hospital department (paediatric, respiratory, etc.), the Poison Information Centre operator can directly provide information in their EHR or by phone about the conditions of the patient and the potential sources of poisoning. The Poison Information Centre operator can add a digital note on the next steps. As part of the Landspítali – University Hospital, the Poison Information Centre is granted access to the surveillance system with an overview of the emergency department. This allows the operator to monitor whether patients follow the given recommendations.

In the case of a more severe CBRNe[52] threat, the Poison Information Centre team has different resources to support its assessment and response. An internal check-list (Appendix 1) has been made for hotline responders to collect the necessary information and follow a defined course of action to ensure the threat is handled appropriately (e.g. engaging professionals from other sectors)[53]. The Poison Information Centre has access to different databases and databanks to look for information on ingredients, toxicity, features of poisoning, management of acute poisoning and treatments (*TOXBASE®*, *Micromedex* and the Norwegian Poison Information Centre). Additionally, the Icelandic Poison Information Centre has developed its own response protocols for threats unique to Iceland, complementary to those of the Swedish Poison Information Centre currently used. In case none of the abovementioned sources of information helps manage the threat, and thanks to its close collaboration with Nordic countries, the Icelandic Poison Information Centre can call directly six different expert institutions (from the Nordic Association of Poison Centres) to discuss the case.

Depending on the severity of the CBRNe threat, the intervention is mostly operated and managed by the Icelandic Police and the Emergency Department of the Landspítali – University Hospital. The expert of the Poison Information Centre is notified and reached by phone for the assessment of the severity of the situation, support its management and give instructions. The Poison Information Centre works closely with the IEEA to monitor chemicals present in Iceland[2] and chemical threats caused by volcanic eruptions (ashes and gas classified as poisonous substances).

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[52] *A CBRNe incident is an emergency situation involving chemical, biological, radiological or nuclear substances, possibly combined with explosives (to spread these substances). The 'explosive' element of these risks was not the subject of a dedicated interview, nor any questions relating to this aspect were asked to the Icelandic experts potentially concerned during the interviews. This is why, although this aspect is now an important element in the definition of CBRN threats, the 'explosive' aspect will not be covered in this report.*

[53] *Additionally, the Poison Information Centre has at its disposal the CBRNe National plan (page 69, including a list of professionals to contact).*

c. Legislation and strategy

Alongside the IEEA, the Poison Information Centre is designated as the national body for chemical surveillance. The Act on Chemicals (No.45/2008) mandates the Poison Information Centre to submit information related to emergency health responses involving chemicals. Under the Chemicals Act (No.61/2013, amended last in 2024), the Poison Information Centre is responsible for managing chemical safety and responding to chemical incidents, under the supervision of the IEEA.

Additionally, the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CPL Regulation) (No.1272/2008, amended last in 2024) requires Member States to designate bodies responsible for receiving information on hazardous mixtures to support emergency health responses. In Iceland, the Poison Centre fulfils this role, ensuring that medical personnel have access to essential chemical composition data in poisoning emergencies.

By the different objectives of health-related legislation, the Poison Information Centre support the collaborative effort by providing information and assistance related to toxic exposures. The Act on the Directorate of Health and Public Health (No.41/2007, amended last in 2022) is a governance act of healthcare services in Iceland, including the emergency response systems. The activities of the Poison Information Centre, operating under the Directorate of Health, align with the act's objectives by offering specialized information and emergency assistance in cases of poisoning, thereby contributing to the overall health services infrastructure.

The Regulation on reporting of communicable diseases and agents posing a threat to public health (No.221/2012, amended last in 2023), mandates the reporting of communicable diseases and other agents that pose a threat to public health. Although primarily focused on infectious diseases, the regulation encompasses any agent that could endanger public health and mentions procedures for managing health emergencies, including toxicological incidents. In this context, the Poison Information Centre serves as a supporting resource for healthcare professionals and authorities by providing information on toxic exposures and facilitating the reporting of incidents involving hazardous agents. Additionally, the Regulation on infection prevention control measures (No.817/2012, amended last in 2024), details measures for controlling communicable diseases. While its primary focus is on infectious agents, the principles of monitoring and controlling agents that pose a risk to public health can extend to chemical exposures. In that regard, Landspítali – University hospital operates an Infection Control Department which registers infections to promote infection prevention within the hospital. The Poison Information Centre contributes to these efforts by offering expertise in managing and reporting on cases of chemical exposures, thereby supporting public health initiatives.

The CBRNe National Plan (2020) includes poisoning as a significant public health threat, outlining various causes, emergency response measures, and preventive strategies. Poisoning is classified into different categories based on its origin, including toxic chemical exposure, foodborne contaminants, bacterial toxins, and hazardous environmental substances. The document details emergency response protocols, including risk assessment, medical intervention, and coordination between healthcare providers and emergency services. Additionally, foodborne poisoning is highlighted, particularly cases linked to bacterial toxins, toxic fungi, and harmful algae. The plan highlights past outbreaks in Iceland and emphasizes public health surveillance, rapid detection, and containment to prevent widespread illness. It

also promotes monitoring, regulatory oversight, public health education, and interagency cooperation to reduce poisoning risks.

Under current legislation, the Poison Information Centre holds numerous responsibilities. However, it faces limited human resources, relying on a single national expert supported by the clinical pharmacists and physicians of the Emergency Department of the Landspítali – University Hospital, trained for handling by phone the first response to a poisoning case. Each year, two clinical pharmacists are trained by the expert to be added to the call centre, but the expert remains the only person capable of responding to requests and cases requiring specialized knowledge. Relying on a single expert creates challenges in balancing time between teaching and other responsibilities. As a result, individuals interested in this field are often forced to pursue studies abroad due to the limited training opportunities available in Iceland which further increases the shortage of toxicology-trained professionals in the country.

V. Nuclear and radiological threats

To date, Iceland has never operated any type of nuclear reactor or nuclear facility and there are no plans to do so, either for energy production or for research purposes. This is reflected in the nation's legal framework governing radiation protection. Iceland's energy needs are primarily met through renewable energy sources, specifically geothermal and hydroelectric power.

a. Key actors and stakeholder networks

The **Ministry of Health** *(Heilbrigðisráðuneytið)* is responsible for the administration and policy making in the field of health, including the enactment of laws and regulations. Additionally, the Ministry regulates mandatory reporting and authorisation for certain radiation equipment producing non-ionizing radiation. It is also responsible for radiation protection regulations, as well as the handling of radioactive substances and radiological equipment.

The **Icelandic Radiation Safety Authority** (IRSA – *Geislavarnir ríkisins*) operates under the jurisdiction of the Minister of Health. It is the primary body responsible for overseeing radiation protection and safety measures against radiation from radioactive substances and radiological equipment in Iceland, ensuring compliance with national and international regulations. It oversees the use of radiation and radioactive materials, conducts environmental monitoring and inspections on the use of radioactive or radiological materials, and assesses radiological risks. Additionally, it coordinates responses to radiological emergencies in collaboration with national and international bodies.

The **National Commissioner of the Icelandic Police** (NCIP – *Ríkislögreglustjóri*) runs the Department of Civil Protection and Emergency Management (*Almannavarnadeild og neyðarstjórnun*) which is responsible for the daily administration of Civil Protection matters. The day-to-day functions of the Department of Civil Protection and Emergency Management include risk analysis and mitigation, coordination of response (i.e. planning, training and equipment) and recovery. The NCIP maintains a National Crisis Coordination Centre[54] which can be activated at any time and is responsible for its operationalisation in emergencies, including nuclear threats. The role of the NCIP during emergency operations is to procure and deliver all outside assistance (national or international) to affected areas.

The **Icelandic Meteorological Office** (IMO – *Veðurstofa Íslands*) is a governmental institution under the Ministry of the Environment and Natural Resources, which primarily focuses on monitoring and forecasting weather and natural hazards. IMO has an expert consultative role in the development and validation of monitoring plans and action plans. It supports nuclear and radiological monitoring in Iceland by providing meteorological data. It monitors atmospheric conditions and supplies real-time data to track and predict the dispersion of radioactive materials in the event of a nuclear or radiological incident. Additionally, it supports emergency response efforts by providing weather forecasts and atmospheric data, which are vital for assessing the spread of radioactive substances and planning appropriate responses.

The **Icelandic Coast Guard** (ICG – *Landhelgisgæslan*) is the agency responsible for search and rescue, maritime safety and security surveillance, and law enforcement in the seas

[54] *Since the performing of the current EU-HIP exercise, the 'National Crisis Coordination Centre' has changed its name to the 'Coordination and Control Centre'.*

surrounding Iceland. With the introduction in Iceland of US nuclear submarines, it plays a supporting role in monitoring them.

b. Digital infrastructures and systems

i. Data sources and systems

In the country, radiation monitoring is performed via:

- A station operated by the Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO), located at IMO. This station continuously monitors airborne particulates. Air samples are collected over a 24-hour period, then stored for another 24 hours, followed by a 24-hour measurement phase. The data is subsequently sent to CTBTO's headquarters in Vienna, for detailed analysis. Iceland serves as a subcontractor to the CTBTO, maintaining access to all the collected data while relying on CTBTO experts for detailed analysis. These experts notify Iceland if adjustments are needed in measurement or collection times. The CTBTO operates a global network of stations, which enables triangulation of radiation events by measuring data from multiple locations. While this process ensures thorough examination, it may introduce some delay in detecting immediate changes.
- A network of four gamma monitoring stations in collaboration between IRSA and IMO. These stations continuously measure gamma radiation levels, integrating their data with meteorological information to enable comprehensive assessments. Although the stations provide real-time data, they only deliver the raw number of gamma radiation level counts without additional specific information. The data collected from these stations are transmitted to the European Radiological Data Exchange Platform (EURDEP) and are also accessible on an internal website for both historical and real-time viewing, with updates approximately every five minutes. Given Iceland's typically low background radiation levels, any significant increase would be immediately noticeable. A system has now been implemented at these four gross gamma stations to alert IRSA experts via email if radiation counts exceed a certain threshold.

Iceland also has a dedicated program for sampling food and environmental elements. These samples are measured for radiation, though this process involves some delay.

- Seawater samples are collected twice a year in February and May by the Marine and Freshwater Research Institute (MFRI) from different locations around the Icelandic Sea and shared with IRSA for laboratory analysis. These samples, typically around 200 litres each, are chemically treated to extract particulates to which *Caesium-137* (Cs-137) binds and then measured with a high-purity *Germanium* (HPGe) detector to determine the concentration of Cs-137, usually finding 1-3 Becquerels (Bq)/m^3.
- Fish samples are obtained from fish stores and sent by MFRI, providing detailed location information. Only Cs-137 is measured, and radioactivity in fish is usually minimal, often below detection limits and typically under 1 Bq/kg.
- Annual seaweed collection from Westman Islands (*Vestmannaeyjar*), which is dried, powdered, and measured, typically yielding below 0.5 Bq/kg of Cs-137.
- Monthly milk samples from two dairy farms around the country are measured, currently only for Cs-137, usually finding between 0.1 and 0.5 Bq/l. Milk samples come from different farms, but specific farm origins are unknown. The samples are broadly categorized by region, such as North or South. Milk is collected and combined by producers. Milk powder is also sourced, usually measuring higher at 3-5 Bq/kg due to water removal.

- Lamb meat is collected annually during fall from various slaughterhouses, often with farm origin information. However, due to free-ranging practices, the exact locations during the lambs' lifetimes are unknown. Lamb meat typically shows slightly higher Cs-137 levels but levels remain very low.

It should be noted that while natural radionuclides may be present in these samples at higher concentration, only Cs-137 is measured at this time.

The system presently in place is largely manual, involving a paper-based form that accompanies each sample through various stages of analysis. The stages include the reception of samples, where they are placed into calibrated containers, weighed and measured. This information is recorded on a paper form. Following this stage, the sample, along with its accompanying form, is taken to the measurement laboratory for analysis. Once the sample has been counted, it is marked and stored. The paper form is then brought to the IRSA office where the data is entered into an Excel sheet. The form itself is also annotated with the results and placed into a different folder for record-keeping. Despite the current reliance on manual processes, there are intentions to digitize the system in the near future. However, no specific plans are yet in place. The institute is also planning to move to a new facility soon. The relocation presents an opportunity to design and implement a more digital-friendly workflow that aligns with the new laboratory setup.

IRSA is responsible for maintaining a detailed registry of radioactive sources in Iceland. All data are recorded in a customer management system and linked through an internal database. For safety and security reasons, this system is not open source. This registry adheres to the International Atomic Energy Agency (IAEA) categorization system, which classifies radioactive sources based on their level of risk and potential for harm. The IAEA categorisation helps ensure that radioactive sources are managed and controlled appropriately, depending on their category and associated risk. IRSA's registry includes information on the types, quantities, and locations of radioactive sources within the country.

United States (US) nuclear submarine

When a US nuclear submarine (submarine powered by a nuclear reactor) is set to enter Icelandic waters, the US Navy notifies the Icelandic Ministry for Foreign Affairs (*Utanríkisráðuneytið*), usually with a few weeks' notice. The Ministry for Foreign Affairs informs then the NCIP with at least a week's notice, and the rest of the emergency preparedness team (consisting of coordinators from each stakeholder involved in the preparation for the arrival of the submarine) receives a 48-hour notice. This short notice period often leads to a rush in preparations. The US Navy provides a rough plan detailing their entry into Atlantic waters, coordinates, anchoring locations, duration of stay and departure plans. However, these plans are usually subject to change.

Upon receiving the coordinates, simulations using the *Argos* program, which predicts reactor breaches and nuclear material release based on weather patterns, are initiated. If simulations indicate significant fallout on land due to current weather conditions, a request is made for the submarine to move, which is usually accommodated. The *Argos* simulations are run every four hours before the arrival of the submarines and hourly from different locations while the submarine is in Icelandic waters. Since the acquisition of *Argos* in February 2023, prompted by the announcement of US submarine visits, simulations are run daily at various locations across the country to build a dataset based on different weather patterns. Although the dataset

is still growing and not all data is permanently stored, these simulations are crucial for maintaining readiness and improving response strategies[55].

Mobile gamma spectrometers, provided by the US Department of Energy, are deployed by the Icelandic Coast Guard for radiation monitoring. One spectrometer is installed on a ship tracking submarine activity, while another is mounted in a vehicle patrolling the coastline. These spectrometers transmit real-time data, including gamma spectra and GPS coordinates, every second to a specialized software, *iAVID*. This software, also developed by the US Department of Energy, enables IRSA to monitor radiation levels remotely, analyse detected radionuclides, and assess anomalies in real-time from their office.

ii. Data sharing

Iceland has initiated the process of entering its information into the IAEA's Emergency Preparedness and Response Information Management System (EPRIMS). This system is designed to enhance global readiness and response capabilities by providing a centralised platform for sharing critical data. The system allows Member States to record information about their emergency preparedness and response arrangements, perform a self-assessment of their status with reference to the recommendations outlined in the IAEA Safety Standards on emergency preparedness and response and, at their discretion, share information and knowledge with IAEA and other Member States.

To facilitate international information exchange, the country also utilises the Unified System for Information Exchange (USIE), a secure website managed by the IAEA, complementary to the EPRIMS. This platform allows countries to send urgent notifications and follow-up information during emergencies and is specifically designed for international communication and information dissemination.

Iceland also shares data with the Incident and Trafficking Database (ITDB) maintained by the IAEA for tracking and managing incidents involving illicit trafficking and other unauthorized activities involving nuclear and other radioactive materials. These platforms provide standardized and formalized procedures for reporting and managing significant radiological events.

Iceland can receive support from the Response and Assistance Network (RANET), an international system established by the IAEA to provide prompt assistance in the event of radiological or nuclear emergencies. It facilitates international cooperation by enabling countries to request or offer expert support, specialized equipment, and technical guidance during such incidents. The network includes capabilities such as radiation monitoring and assessment, medical advice and treatment for radiation exposure, environmental contamination assessment and remediation, as well as emergency planning and response coordination.

Additionally, and as previously mentioned, Icelandic data is shared with EURDEP to support broader European monitoring efforts. To ensure compatibility with EURDEP, the data must adhere to specific harmonisation standards. EURDEP serves as the EU's official platform for exchanging radiological data during emergencies. However, data is continuously and automatically shared, always ensuring its availability and minimizing the additional effort

[55] *The Argos simulation program, developed in Denmark, is widely used by many countries and distributed under strict licensing agreements to ensure security. There is a user group, attended by the Icelandic IRSA team, that meets several times a year to discuss usage and best practices.*

required during emergencies. Under normal (non-emergency) conditions, the collected data primarily represent the current natural radiation background. It is important to note that EURDEP is not a rapid alert system. The early notification of radiological accidents or emergencies is managed through the European Community Urgent Radiological Information Exchange system (ECURIE), operated by the European Commission on a 24/7 basis[56] or via USIE, as mentioned above.

The radiation safety authorities in the Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden) have collaborated extensively for decades, focusing on radiation emergency response planning and management. This collaboration includes the Nordic Nuclear Safety Research (NKS), which has facilitated joint Nordic research projects and seminars.

iii. Reports

Institutions in Iceland report to their respective ministries. IRSA holds regular meetings with the Ministry of Health, as well as additional meetings with the Financial Office Department of the Ministry, four times a year. These meetings can be both regular and ad hoc, ensuring consistent communication and updates.

Publication of collected data is not presented via any dashboards, which is seen as a potential future enhancement but not an immediate necessity. The development of such a tool is hindered by the lack of resources. Reports on monitoring of the environment and food are, however, published on the IRSA website. The last report covered the year 2015, but a new report covering the years 2016 to 2020 is expected to be published in 2024-2025 in both English and Icelandic. Additionally, a report for the years 2021 to 2023 is anticipated by the end of 2025. Moving forward, the goal is to resume the annual publication of these reports and make them publicly accessible.

iv. Threat indicators

In the event that significantly higher levels of radioactivity are detected during routine monitoring, the initial response involves re-measuring the sample to confirm the readings and rule out any measurement errors. Once elevated radioactivity levels are confirmed, an internal meeting with the environmental monitoring team and the emergency preparedness team of IRSA is convened to assess the situation. The primary objectives are to determine the validity of the readings, identify potential sources of contamination and understand the extent of the issue. If elevated readings are observed consistently across multiple samples over a period, the presence of contamination is suspected. In such cases, the internal teams work collaboratively to locate the source of contamination and assess its nature.

Notification of relevant stakeholders, such as the Chief Epidemiologist and public health authorities, is an essential part of the response process. Given the small number of stakeholders involved due to the population size of the country, the practice of informal, person-to-person communication is prevalent. Regular contact, typically once or twice a month, helps maintain coordination among the different authorities. The current communication system relies on direct phone calls for urgent matters, followed by an e-mail, ensuring a written record for reports. This method, while effective in small-scale operations, lacks a dedicated and systematic communication framework.

[56] *EUropean Radiological Data Exchange Platform (EURDEP) – Radioactivity Environmental Monitoring - Joint Research Centre (EUropean Commission)*

In the case of a major radiological incident, the response protocol involves engaging international stakeholders and channels such as the IAEA and the USIE.

v. Medical countermeasures

The Chief Epidemiologist supervises the delivery, distribution and use of safety stocks of medicinal products, and other necessary equipment in the country to respond to health threats such as epidemics or other emergencies. Specifically for iodine tablets, a plan is currently being developed[57].

Currently, there is no formalized or legislative mandate concerning MCM for radiological threats, as such threats were previously considered non-existent in Iceland. However, there is enough personal protective equipment (PPE) to provide personal dosimeters to first responders in the event of an incident. First responders would be informed by IRSA on what to look for and how to protect themselves.

[57] *Regulation on infection prevention control measures (No.817/2012) - Article 7*

c. Legislation and strategy

The Act on Radiation Protection (No.44/2002, as amended in 2018), aims to ensure the protection of individuals, society and the environment from the harmful effects of ionizing and non-ionizing radiation. It establishes IRSA as the primary regulatory body responsible for issuing licenses and monitoring compliance with safety standards. The Act sets forth requirements for radiation safety and mandates regular monitoring of radiation levels in various environments. License holders are required to ensure the safety of their operations, implement safety measures, conduct regular risk assessments and maintain detailed records of radiation exposure. In terms of emergency preparedness, the Act establishes protocols for responding to radiological incidents, emphasizing collaboration with national and international bodies to manage and mitigate such events.

Currently, the Act is being updated, overseen by a specially appointed committee by the Ministry of Health, supported by 15 consultations to gather diverse input from multiple stakeholders. The draft was planned to enter public consultation in the summer of 2024 for public consideration and feedback. The public consultation process is open to all individuals with an Icelandic ID number (*kennitala)*, increasing transparency and public participation in regulation and decision-making. Additionally, it provides deeper insights that may not emerge during stakeholder meetings as participants might not fully express their views due to various constraints. The bill, along with all feedback and responses, is then published. The Ministry of Health will subsequently incorporate relevant input before submitting the final draft to Parliament.

Several significant changes are proposed in the new legislation, particularly concerning sanctions and regulatory authority. The current law, over 20 years old, lacks adequate provisions for IRSA to enforce sanctions effectively. Under the new act, IRSA's role and authority will be clearly defined, enabling it to impose fines and take corrective actions when radiation safety regulations are breached. The new bill also introduces a tiered system for radiation protection officers based on the risk level associated with different industries. This system will categorize officers into three levels, with responsibilities varying according to the risk level. Higher-risk industries will require more specialised and higher-level radiation protection officers.

The updated legislation is expected to have varying impacts on different institutions. Major hospitals and large clinics, which already have robust radiation safety plans in place, will experience minimal changes. However, the new regulations will significantly affect smaller facilities like skincare clinics. These clinics, which currently only need to report when importing equipment, will now be required to have such equipment licensed and registered.

Funding for these activities is addressed within the bill to be presented to Parliament. Alongside the bill, a financial assessment outlining the bill’s impact will be provided. IRSA generates income through inspection fees, as detailed in their price list. This aspect, already part of the existing Act on Radiation Protection, will be further clarified in the new bill.

The bill does not specifically address medical countermeasures. Instead, it focuses on the technical aspects of radiation protection and the preparedness roles of the radiation authorities.

Additional relevant legislation include[58]:

- Regulation No.1299/2015 deals with radiation protection in medical uses of X-rays
- Regulation No.1298/2015 covers the use of sealed sources
- Regulation No.1290/2015 covers limits of radiation exposure of workers and the general public with respect to activities involving the use of radiation
- Regulation No.809/2003 with amendment No.920/2003 covers the use of open sources
- Regulation No.738/2003 on waste landfill, which prohibits the disposal of radioactive waste in landfill
- Regulation No.810/2003 on sunlamps
- Regulation No.1339/2015 with amendment No.1079/2017 on the import and use of lasers, laser pointers and IPL devices

In addition, the following apply:

- Act No.20/1972 on the prohibition of release of dangerous materials to the ocean
- Act No.33/2004 on the prevention of pollution of the coast and the ocean
- Regulation No.1077/2010 on the transport of dangerous goods on land

International regulation and conventions that apply to the country:

- Iceland became a signatory to the Convention on Nuclear Safety in September 1995, and it came into effect for the country in September 2008;
- Convention on Early Notification of a Nuclear Accident entered into force on October 1986

The CBRNe National Plan (2020) addresses various response stages for CBRNe incidents. It details a structured response approach, including initial risk assessment, decision-making processes, and escalation of response levels. Regarding radiological and nuclear threats, the document discusses international cooperation frameworks, including established guidelines such as the Protective Measures in Early and Intermediate Phases of a Nuclear or Radiological Emergency – Nordic Guidelines and Recommendations, which provide guidance for determining safety zones and response measures. Additionally, the document outlines specific emergency response procedures, including information-sharing mechanisms among national and international organizations. It emphasizes the importance of timely risk assessments and the implementation of protective actions to mitigate the impact of radiological and nuclear incidents.

Radiological emergency preparedness and response in Iceland is guided by the safety standards and framework for emergency preparedness and response established by the IAEA. The nearest nuclear power plant is over 1,000 kilometres from Iceland, making it highly unlikely that a nuclear accident at such a plant would have a significant health impact on the country. Most likely, accidents at these plants would not necessitate a public health response in Iceland. However, incidents involving nuclear-powered vessels near Iceland or the re-entry of nuclear-powered satellites could have localized but substantial impacts[40]. The presence of US nuclear-powered submarines in Icelandic waters is a recent development, shifting the focus on CBRN to include more radiological preparedness.

[58] *Iceland national report: eighth and ninth review meeting of the contracting parties to the convention on nuclear safety. Iceland Radiation Safety Authority - International Atomic Energy Agency (November 2023).*

The *Argos* simulation program enables long-range simulations. While Iceland has not conducted those types of simulations, data from the Danish, Swedish, and Norwegian exercises is shared. These simulations indicate that in a worst-case scenario, it would take at least a week for any contamination from a European nuclear event to reach Iceland. By then, measures such as distributing iodine tablets would be unnecessary, as the radioactive iodine would have decayed.

Each agency involved in radiological monitoring and emergency preparedness conducts tabletop discussions, though no large-scale exercises involving first responders. Currently, simulations are not mandated by legislation. However, planning discussions about preparedness have been ongoing since the visits from US nuclear submarines began. Exercises are planned for the near future, though the scale remains undetermined.

International exercises are conducted through the IAEA. These exercises occur a few times a year, and efforts have been made to include observers from health authorities and civil protection authorities. However, these exercises mainly focus on communication rather than full-scale operational readiness. Small exercises with civil protection authorities are held annually, primarily to promote familiarity among participants. These exercises are informal and do not generate formal reports, though formalizing this process is under consideration.

Training in radiation safety for first responders is not formalized, though there has been some legislative change in progress, addressing aspects of their technical training. While there have been training sessions for the Fire Department, these have not been conducted on a regular, formalised basis. Training sessions are available on request to any company or individual interested in radiation safety.

IRSA is responsible to inform and educate the public about radiation threats. This includes providing information and alerts in case of any radiation dangers, and ensuring public awareness and safety.

VI. General preparedness

The following chapter will provide a broader perspective on preparedness activities that apply across various threats.

a. Key actors and stakeholder networks

The **Minister of Justice** (*Dómsmálaráðuneyti, previously: Ministry of the Interior*) is the supreme authority for civil protection matters.

The **Civil Protection Council** formulates government policy on civil protection and security in five-year cycles. It is composed of government ministers and their permanent secretaries, representatives from local authorities, leaders of critical infrastructure sectors, volunteer organizations, and civil protection agencies. Chaired by the Prime Minister, the Council's policy outlines the current state and future outlook of civil protection and security. This includes measures for prevention, preparedness, response coordination, recovery efforts, essential stockpiles for national survival during disasters, the functioning of public infrastructure, and other key actions deemed necessary under the Civil Protection Act.

Civil protection in Iceland falls under the Ministry of Justice. Civil Protection responsibilities at the national level are delegated to the **National Commissioner of the Icelandic Police** (NCIP – *Ríkislögreglustjóri*). The NCIP runs the **Department of Civil Protection and Emergency Management** (*Almannavarnadeild og neyðarstjórnun*) which is responsible for the daily administration of Civil Protection matters.

The **Department of Civil Protection and Emergency Management**'s day-to-day functions include risk analysis and mitigation, coordination of response (i.e. planning, training and equipment) and recovery. It employs an '*all-hazards*' approach for a unified response to emergencies, regardless of type, allowing agents to act immediately without categorizing incidents. While the police oversee emergency local response, management relies on cross-sector collaboration, with the Department handling centralized coordination.

The **National Crisis Coordination Centre**[59] is a standby structure activated for major emergencies (e.g. volcanic eruptions, pandemics, or complex rescues). It is not continuously staffed but follows a clear activation protocol based on emergency response needs. The Centre is organized in three tiers: national coordination (led by the National Crisis Coordination Centre), district coordination (managed by Iceland's nine police and civil protection districts), and on-scene coordination (where responders handle operations directly). The composition of the National Crisis Coordination Centre is flexible, with a core group of fixed agencies and the ability to include additional experts as needed, depending on the nature of the crisis.

The National Crisis Coordination Centre is overseen by an eleven-member board chaired by an appointee of the Minister. Board members are nominated by key national agencies. The board is responsible for decisions related to internal organisation, inter-agency cooperation, and the operational structure of response agencies. However, it does not directly coordinate or implement emergency operations.

The **Civil Protection Scientific Advisory Board** is convened during crises and consists of specialists from the Icelandic Meteorological Office, the Institute of Earth Sciences, the

[59] *Since the performing of the current EU-HIP exercise, the 'National Crisis Coordination Centre' has changed its name to the 'Coordination and Control Centre'.*

Environmental and Energy Agency, the Directorate of Health, the Occupational Safety and Health Agency, and the Food and Veterinary Agency[60]. The role and functionality of the Civil Protection Scientific Advisory Board are currently being reviewed to ensure it meets the current needs for crisis management.

The **Civil Protection Committees** are appointed by each local government, and they are responsible for developing policies and organizing civil protection activities at the regional level. They collaborate with the NCIP to prepare risk assessments and preparedness plans for their areas. Additionally, they review these assessments and conduct tests of the preparedness plans in partnership with the NCIP.

While the police serve as a national organisation, the **Fire and Rescue departments** operate at the local, and municipal levels. They are the first local actors to handle emergency response to accidents thanks to their expertise and training.

The **Icelandic Coast Guard** (ICG – *Landhelgisgæslan*) is the agency responsible for search and rescue, maritime safety and security surveillance, and law enforcement in the seas surrounding Iceland.

The **Icelandic Search and Rescue** (ICE-SAR) is a volunteer-based organization that specialises in search and rescue operations, responding to emergencies in challenging terrains, including maritime rescues and avalanches.

The **Red Cross** provides mass care, shelters, and psychosocial support, and operates Helpline 1717 for crisis assistance.

Iceland is actively engaged in international cooperation on civil protection and disaster response, despite not being a member of the European Union. It participates in the European Civil Protection Mechanism alongside Norway and other non-EU countries. This collaboration provides access to training opportunities, and Iceland also contributes its expertise by sending trainers and responders to disaster zones. Participation in the European Civil Protection Mechanism also supports Iceland in addressing gaps in its domestic stockpiles and capabilities for handling CBRN incidents.

Additionally, Iceland is involved in Nordic cooperation under the North Threat Initiative, the Nordic Health Preparedness (The Svalbard Group), the North Atlantic Treaty Organization, and the United Nations frameworks. Direct bilateral relationships with other nations further strengthen its global ties. However, the demand for Iceland's involvement often exceeds its capacity due to limited personnel. Historically, the team handling these collaborations consisted of five individuals, though this has grown to around 15-20 in recent years.

[60] *Iceland overview – The national disaster management system – Civil Protection. European Civil Protection and Humanitarian Aid Operations – European Commission.*

b. Digital infrastructures and systems

i. Data sources and systems

The NCIP relies on a set of tools and strategies to manage emergencies and maintain an overview of tasks during crises. The overall coordination is supported by a web-based software system, used locally and in several other countries. This system allows for real-time task tracking, decision logging, and progress updates, ensuring seamless collaboration across stakeholders.

Currently, there are plans to construct a new purpose-built infrastructure to support the activities of the National Crisis Coordination Centre, however, long delays have slowed this process.

ii. Threats assessment

The NCIP is responsible for declaring an emergency and alert levels at any given time. This decision is made in consultation with the relevant regional police commissioner and the Minister of Justice is informed.

When activated, the National Crisis Coordination Centre operates on a phased activation system, with three levels of escalation depending on the severity of the situation. Once activated, regular coordination meetings are held to assess the situation, plan responses, assign tasks, and review progress.

1. *Uncertainty phase;* is characterized by an event which has already started and could lead to a threat to people, properties, communities or the environment. At this stage, the collaboration and coordination between the Civil Protection authorities and stakeholders begins. Monitoring, assessment, research and evaluation of the situation is increased. The event is defined, and a hazard assessment is conducted regularly.
2. *Alert phase;* if the hazard assessment indicates an increased threat, immediate measures must be taken to ensure the safety and security of those who are exposed. This is done by increasing preparedness of the emergency and security services in the area and by taking preventive measures, such as restrictions, closures, evacuations and relocation of inhabitants. This level is also characterized by public information, advice and warning messages.
3. *Emergency phase;* is characterized by an event which has already begun and could lead, or has already led to, harm to people, communities, properties or the environment. At this stage, immediate measures are taken to ensure security, save lives and prevent casualties, damage and loss.

When an emergency arises, notifications are sent to assemble an appropriate response team. The system is organized in three tiers: national coordination (managed by the National Crisis Coordination Centre), district coordination (handled by Iceland's police and civil protection districts), and on-scene coordination (where first responders manage operations directly at the site). A key challenge within this approach is the lack of dedicated personnel assigned exclusively to the National Crisis Coordination Centre. While there is no official appointment process, the National Crisis Coordination Centre maintains a semi-formal roster of trained personnel. Each contacted stakeholder decides whom to send when called upon, sometimes at the expense of continuity and structure in the management of threats.

During an emergency, the NCIP in coordination with the National Crisis Coordination Centre, is responsible for informing the public about ongoing events and providing guidance. Information is disseminated through various channels, including social media, news outlets, and the National Crisis Coordination Centre's official website, ensuring broad public reach. A communication officer within the National Crisis Coordination Centre leads these efforts, working closely with media officers from other agencies to maintain unified messaging and ensure efficient information distribution. Additionally, alert messages are sent out to mobile phones in the affected area using cell broadcasting via cell towers.

After an emergency, the Department of Civil Protection and Emergency Management under the NCIP must convene a review meeting within one month with all involved response parties. This meeting allows stakeholders to evaluate the quality of the response, and official minutes are documented and shared with relevant parties, including the minister. The NCIP is also responsible for ensuring that necessary improvements are implemented. In addition, the National Crisis Coordination Centre's board may commission an external expert review of the response, either after the internal review or earlier if justified. The Minister may also independently initiate such a review if the board's report is deemed insufficient. These reviews must be conducted by experts without conflicts of interest.

A significant challenge in Iceland's crisis management efforts lies in staffing. Many divisions are short-staffed, with single individuals responsible for multiple tasks. When such a person leaves, it creates a gap in expertise that is difficult to fill. While there are individuals who can temporarily take over these roles, they may not have the same level of knowledge, which can hinder the effectiveness of preparedness efforts. In contrast, as many professionals are assuming multiple roles, individuals often possess broad, general knowledge across multiple areas, enabling them to tackle diverse tasks.

c. Legislation and strategy

The Civil Protection Act (No.82/2008, last amended in 2025) in Iceland mandates the identification, analysis, and reduction of risks to safeguard lives, property, and the environment. The Act stipulates that Civil Protection Committees in the municipalities should investigate the resilience in their districts and make preparedness plans according to their risk assessment, which must be regularly performed to reflect emerging threats and vulnerabilities. This includes identifying potential hazards such as volcanic eruptions, severe weather events, and other natural risks, as well as human-made threats, and how they could be addressed. The Act specifies that the NCIP is responsible for overseeing and coordinating emergency management efforts at the national level, while police commissioners at the local level manage operations during emergencies. Currently, the Act is under revision.

Risk assessments

The first National Risk Assessment in Iceland was performed in 2008-2011. All the 15 Civil Protection Districts with 74 municipalities in Iceland were engaged in the assessment that was led by the Department of Civil Protection and Emergency Management at the Office of the NCIP and in collaboration with the local civil protection authorities. The primary objective of the risk assessment was to gain an overview of hazards in each of the 15 Civil Protection districts in Iceland, and to identify, analyse, and evaluate associated risks. Additionally, the assessment aimed to raise risk awareness, implement mitigation measures, and enhance preparedness, ultimately strengthening community resilience. The analysis had an all-hazard approach focusing on registering risk with diverse origins at a local and national level. For each risk evaluated, there was a scenario analysis that looked at the possible event, previous events, the likelihood, the impact and consequences, responsible monitoring agency, mitigation and preparedness measures, emergency response measures, recovery measures and lessons learnt.

By involving experts from different sectors and disciplines the Civil Protection committees in the Civil Protection Districts were able to assess risks in their immediate environment, share a common understanding of the challenges they faced and decide which measures in prevention and preparedness to use to address the risk to treat they had identified[61].

A formal, overall national risk assessment has not been conducted since; however, several documents have been prepared outlining the governmental strategy on civil protection and security (the latest in 2021). Additionally, a report was published by the Prime Minister in 2022 on emergency stockpiles in Iceland (food, gasoline, medication, etc.). Although it does not list clear risks or plans for improvement, it addresses vital issues that need to be considered with regard to emergency stockpiles.

Preparedness plans

A central aspect of the Civil Protection Act and further defined in the Regulation on the content and preparation of contingency plans (No.323/2010), is the development of preparedness or response plans. These plans follow a standardized format, ensuring consistency across various scenarios. Plans are threat-specific rather than institution-specific but involve all relevant stakeholders. Each plan outlines responsibilities, ensuring coordination among

[61] *National Risk Assessment for Iceland – Executive Summary – Department Of Civil Protection And Emergency Management – The National Commissioner Of The Icelandic Police (2011)*

agencies and avoiding redundancy or conflicting actions. Agencies are encouraged to create their own detailed protocols or checklists tailored to their specific tasks, but these must align with the overarching national plan.

Development and maintenance of these plans fall under the Civil Protection Committees in collaboration with NCIP, with regular reviews conducted every four years. These reviews are often accompanied by exercises to test the plans and refine them based on real-world applications. The exercises are conducted regularly, with 4 to 12 exercises organised annually. These simulations address various potential threats, with a strong focus on mass casualty incidents. After each exercise, an evaluation is conducted to identify strengths and areas for improvement. If, during a response, a more effective approach is identified, it is encouraged to act accordingly as long as it aligns with legal and procedural standards. Though not all exercises result in formal reports, specific recommendations may be formulated and lead to updates in protocols, enhanced training, or procedural adjustments.

Key preparedness documents are available on the Directorate of Health website and include the Pandemic National Plan (2020) focusing on providing a structured response to pandemics, supporting coordination between public health authorities and emergency response agencies, and the CBRNe National Plan (2020) outlining the response structure and coordination for incidents involving CBRNe threats.

Training

Training for the '*all-hazards*' approach, implemented in the country for crisis management, is integrated across various sectors and roles. Police officers receive this training as part of their basic education, and it extends to volunteer rescue units, firefighters, healthcare professionals, and anyone expected to play a role in emergency response. This ensures a unified understanding of the response approach as all participants share the same knowledge.

The standardized training prepares individuals for their roles in the National Crisis Coordination Centre, where diverse sectors collaborate. Previously, training was siloed, with participants focusing solely on their specific expertise while others waited for their responsibilities to arise. Now, the training emphasizes a flexible response process, enabling any trained professional to assist with various tasks. This approach has created a more adaptable and efficient work environment where roles adjust to the needs of the situation.

VII. Medical countermeasures

a. Key actors and stakeholder networks

The **Icelandic Medicines Agency** (IMA – *Lyfjastofnun*) is the regulatory authority responsible for overseeing the import, distribution and oversight of medicines and medical devices in Iceland. Operating under the Ministry of Health, it ensures the quality, safety and availability of medicinal products, as well as monitoring medicine sales in Iceland. The agency evaluates and manages marketing and licensing authorisations, oversees the import and sale of over-the-counter medicinal products, monitors their safety and side effects, and supervises pharmaceutical production and wholesale activities. It also decides the prices of prescription medicines and which medicines are eligible for reimbursement, authorizes clinical trials, regulates medicinal products advertising, addictive substances and the handling of blood, cells and tissues, while ensuring that drug shortages have minimal impact on patient safety. The agency monitors medical devices available in Iceland and supervises incidents involving medical devices. Additionally, the agency collaborates with foreign organizations and carries out tasks as mandated by Icelandic law and European regulations.

The **Directorate of Health** (*Embætti landlæknis*), operating under the Ministry of Health, is the central authority responsible for public health, healthcare services and health promotion in Iceland. The Directorate oversees health surveillance and quality assurance. The Chief Epidemiologist at the Directorate oversees emergency preparedness for public health threats due to epidemics, chemical events or radiation. Specific to MCM, the Directorate has the responsibility to monitor prescriptions and promote reasonable use of medicinal products. In this regard, the Directorate hosts comprehensive health data and registries, including the Prescription Medicines Register. The Chief Epidemiologist has a stockpile of drugs and PPE for emergencies.

The **Ministry of Health** *(Heilbrigðisráðuneytið)* is responsible for the administration and policy making in the field of health, including the enactment of laws and regulations. In addition to its responsibilities regarding disease control and health promotion, the Ministry of Health is responsible for overseeing and regulating the organization and operation of healthcare services, including the distribution and use of medicines and medical devices. The Ministry manages health insurance programs, which affect access to MCM, and the operations of IMA related to medicinal and related products. The Ministry is also involved in planning and coordinating responses to health crises, including the stockpiling and distribution of essential medicines.

The **National Security Council of Iceland** ensures the implementation of the country's national security policy, serves as a consultative forum, assesses security threats and facilitates coordination among ministries. It promotes public education on security issues, reviews policies every five years, and addresses emergencies affecting sovereignty or public safety. Regarding MCM, it consults and coordinates with the Civil Protection and Security Council. This involves assessing health-related risks, ensuring preparedness, and aligning efforts across agencies to protect public safety during crises.

The **National Commissioner of the Icelandic Police** (NCIP – *Ríkislögreglustjóri*) runs the Department of Civil Protection and Emergency Management (*Almannavarnadeild og neyðarstjórnun*) which is responsible for daily administration of Civil Protection matters. The day-to-day functions of the Department of Civil Protection and Emergency Management include risk analysis and mitigation, co-ordination of response (i.e. planning, training and

equipment) and recovery. The NCIP maintains a National Crisis Coordination Centre which can be activated at any time and is responsible for its operationalisation in emergencies. During emergencies, the NCIP is responsible for procuring and delivering necessary assistance, both national and international, to affected areas. This includes medical supplies and resources essential for crisis management.

Healthcare institutions are responsible for prescribing and dispensing medicinal products, ensuring the safe and rational use of medications, and maintaining adequate stocks, especially of essential medicines. Healthcare institutions must monitor and report the use of medicinal products to national registers, such as the Prescription Medicines Register. Institutions are required to comply with national regulations, cooperate with IMA, and contribute data for public health surveillance. Healthcare facilities like Landspítali – University Hospital also maintain a Medicinal Products Committee to oversee the proper use of medicines within the institution. In times of public health emergencies, healthcare institutions support the managing of stockpiles of essential medicines and coordinate with national authorities to ensure the swift distribution of MCM.

The **Medicinal Products Committee** at Landspítali – University Hospital promotes the safe and rational use of medicines across public healthcare institutions. The committee is appointed by the Minister of Health for a five-year term. The committee is responsible for deciding on the use of medicinal products in healthcare services, including licensed products i.e. new expensive medicines and/or in need of a specialist's attention. It evaluates the benefits of these products for patients, creates guidelines, and develops priority lists of medicines, considering financial resources for their adoption and use. The committee also prepares and monitors medicinal lists for public healthcare institutions. Before IMA makes decisions about licensing medicinal products, the committee provides written comments and supporting reasoning. It also submits feedback on the cost-sharing of licensed medicinal products.

Regarding MCM, **pharmacy licence holders** must maintain an adequate stock of medicinal products available in Iceland, quickly obtain medicines that are in demand but not in stock and offer essential medical equipment whenever possible. They are also required to provide IMA with any requested information about the pharmacy's operations. Pharmacies must electronically record all prescription details in the format set by the Directorate of Health and follow the Data Protection Act. Upon request, they must provide the Directorate with prescription information, including details on dispensed medicines, for up to one year. There are 75 pharmacies in Iceland and 25 pharmacy branches.

Pharmaceutical companies are responsible for the manufacture (in Iceland only limited to O_2 manufacturing), marketing, and supply of medicinal products in Iceland. They must ensure that their products comply with the regulatory standards set by the IMA and other relevant authorities, including the proper labelling, packaging, and safety monitoring of medicines. Wholesale authorisation holders who sell medicinal products to pharmacies, healthcare institutions and the workplaces of physicians, dentists and veterinarians are obliged to maintain sufficient stocks of specific necessary medicinal products for which marketing authorisation has been granted in Iceland and which have been placed on the market, and of which the wholesale authorisation holder handles the distribution. They shall maintain and publish medicinal product '*waiting lists*', i.e. lists of medicinal products for which marketing authorisation has been granted in Iceland and which have been marketed, and of which they handle the distribution, but are not available at any given time. They are obliged to inform IMA of impending stock shortages of medicinal products. If a marketing authorisation holder (MAH)

ceases to offer a medicinal product on the market, temporarily or permanently, it shall notify IMA not later than two months prior to ceasing to offer the product on the market unless exceptional circumstances render this impossible. The MAH shall, to the extent that this falls within his responsibility, ensure appropriate and uninterrupted delivery of the product to pharmacies and other entities authorised to dispense the product so as to meet the needs of patients. Additionally, pharmaceutical companies and pharmacies must provide information to the IMA regarding their inventory levels and distribution to help monitor the supply of medicinal products.

Iceland is part of the **Nordic Health Preparedness (The Svalbard Group)**, which aims to enhance cooperation and facilitate the exchange of information, skills and knowledge across the Nordic Region. It focuses on public health and social services in the context of emergency preparedness, crisis and disaster management to improve crisis and disaster handling capabilities. The Svalbard Group is working under The Nordic Council of Ministers and the Nordic Council, which are the main forums for official Nordic cooperation. The activities of the Svalbard Group are based on the Nordic Public Health Preparedness Agreement of 2022, which is committed to assisting one another in times of crisis. While the Baltic countries are not currently included in this group, greater collaboration with them is being considered.

b. Digital infrastructures and systems

i. Data sources and systems

IMA maintains several registers for medicinal products and medical devices in Iceland:

- The **Medicinal Product Information Database** (*Sérlyfjaskrá*) contains information on medicinal products marketed in Iceland, both human and veterinary products. It is organized by the brand name and includes details such as active substances, pharmaceutical form, route of administration, ATC-classification, MAH and its agency and wholesaler in Iceland. The database is accessible both via a webpage and a web service, and is available to the public, businesses, and public institutions. It is possible to search the database in various ways, e.g. by generic name. It provides information such as:
  - Approved summary of product characteristics and package leaflets;
  - Pack sizes available on the market;
  - Whether the medicine is dispensed with a prescription or an OTC product;
  - Maximum retail price;
  - Reimbursement status;
  - Reference products if the medicine is on IMA's substitution list; and
  - Risk minimisation measures.
- The **Medicine Price Catalogue** (*Lyfjaverðskrá*) provides detailed information on each medicinal product, including pack-level pricing. It also includes other relevant data, such as dose dispensing options, medicine classification, reference codes, and Defined Daily Doses (DDD). In Iceland, one of the conditions for selling prescription medicines is that the Icelandic Medicines Agency must approve the maximum wholesale and retail prices. Additionally, information about the medicine must be published in the Icelandic Medicine Price Catalogue. This publication requires submitting a formal request via a specific form.
- The **Register of Medical Device Distributors,** where distributors of medical devices responsible for marketing such devices in Iceland must register with the IMA via an appropriate form. This register ensures that all distributors comply with national regulations[62].
- The **Register of Manufacturers**, authorised representatives and importers based in Iceland[63].
- IMA administers surveillance of all manufacturing firms of medicinal products in Iceland, wholesalers and pharmacies plus other supervised entities. It keeps a record of those parties and published lists on it's website.

As part of the EEA, IMA, along with economic operators of medical devices, notified bodies, and sponsors of clinical studies of medical devices, are required to register relevant data in the European database on medical devices (EUDAMED) or other central European administrative tools (*CircaBC*) until EUDAMED is fully functional. Similarly, data needs to be reported to the EudraGMDP database, the European Medicines Agency (EMA) system for recording manufacturing and wholesale distribution authorisations, as well as Good Manufacturing Practice and Good Distribution Practice certificates.

[62] *Act on Medical Devices (No.132/2020)*
[63] *Act on Medical Devices (No.132/2020)*

The Directorate of Health holds the Prescription Medicines Register which records all dispensed prescriptions nationwide excluding those in hospitals. Discussions are currently underway to expand the register to include hospital pharmaceuticals as well. The database supports the supervision of prescription practices, monitors narcotic and psychotropic substances, and aids in tracking medication costs and forecasting healthcare quality improvements. Prescriptions from veterinarians are also stored in the database. The Directorate of Health is responsible for maintaining the database, while authorized entities can access the information. Via the Prescription Medicines Register, physicians can prescribe medications electronically, review their patients' prescription histories, and monitor dispensed drugs. Accessible through electronic medical records or via a dedicated portal using electronic identification, the database provides up-to-date information on prescriptions and medication dispensing, covering a span of seven years. Patients can also access their medication information securely through the patient portal *Heilsuvera (cf. Pathogens with high pandemic potential – Data sources)*. One of the future development projects is to include also comprehensive information on inpatient medication.

Real-time monitoring

Regarding use and stockpiling, the monitoring of MCM is governed by the Medicinal Products Act (No.100/2020). IMA shall publish on its website a **list of specific necessary medicinal products** (*'the critical list'*), and stock quantities following a consultation with the Directorate of Health, the Landspítali – University Hospital, the Food and Veterinary Authority and wholesale authorisation holders. The list was published in 2022 but without quantities as it is believed that a stronger legal basis is needed. The list is currently being updated and EMA's list of critical medicines is taken into account as well as domestic requirements.

Currently, there is no central database for the inventory of medicines and medical equipment which impedes real-time monitoring. However, the Act allows IMA to inquire about the stock levels and annual sales of medical products from various entities, including hospitals, pharmacies and wholesalers. However, the process relies on ad-hoc requests and is not supported by an information system. The Act also requires that wholesale authorisation holders notify IMA of impending stock shortages of medicinal products which are then listed on a dedicated section of the IMA website. In Iceland, if a medicine cannot be obtained from a wholesaler, it is placed on a waiting list. Recent years have seen both short and long periods of unavailability of important antibiotics. IMA collaborates with Nordic and European partners on this issue. It follows recommendations from EMA and the Heads of Medicines Agencies to address shortages of essential antibiotics. Since 2020, IMA has tracked all human medicine shortage reports. Between 2020 and 2022, there were 2,699 such reports[64].

The National Security Council, which plays a critical role in assessing national security risks, including those related to public health, has identified the need for a more detailed and proactive information-gathering system. To address this challenge, there have been efforts to introduce new legislation that would empower the authorities to collect real-time data on the stockpiling and distribution of MCM. The proposed system would be rolled out in phases, and it would allow monthly updates on the use and stockpiling of MCM. In times of crises, it would provide the Civil Protection and Emergency Management Department with immediate access

[64] *Antibiotic use and antibiotic susceptibility of bacteria in humans and animals in Iceland 2022 – Directorate of Health and MAST (September 2023).*

to critical information, allowing for better decision-making regarding the allocation and distribution of MCM.

Given Iceland's reliance on imported medicines, the role of wholesalers is particularly significant in sharing these data. Ongoing discussions aim to reassure industry stakeholders and wholesalers that the system is intended solely for national security purposes and will not impact their business operations. Additionally, evaluations are underway to assess whether the existing legal framework is adequate or if new legislative measures are needed to implement the system effectively.

National reserve

The Chief Epidemiologist supervises the delivery, distribution and use of safety stocks of medicinal products, and other necessary equipment in the country to respond to health threats[65].

The **safety medicinal stocks list** outlines the medicinal products and intravenous fluids that must always be available in Iceland at all times to respond to health threats. The list is bound in regulation issued by the Ministry of Health and overseen by the Chief Epidemiologist as per Regulation No.817/2012 (Regulation on infection prevention control measures), with reviews conducted at least every five years in collaboration with the Medicinal Products Committee at Landspítali – University Hospital. The Chief Epidemiologist handles allocations from the stock according to a risk assessment. The list is distinct from the critical medicines list, which covers medicines for routine healthcare needs and is maintained by IMA.

Under the Act on Health Security and Communicable Diseases, the country set a national reserve prior to the swine flu outbreak of 2009. Although this stockpile was extensively utilised during the COVID-19 pandemic, the current regulation does not specify the required level of stockpiling per item, so efforts are underway to define them.

The strengthening of a national reserve of stockpiling began during the COVID-19 pandemic when authorities established a task force consisting of permanent secretaries from all ministries. It is planned to develop a three-tiered stockpiling strategy to ensure adequate preparedness. A list of critical medicines is being established and will be used as a baseline across all three tiers. Additionally, scenarios are being developed to guide the creation of MCM lists tailored to specific threats.

- The *first layer* would involve state-owned stockpiles, managed by the Chief Epidemiologist. This tier will focus on essential medicines that need to be available in the country for crises.
- The *second layer*, also state-owned, pertains to hospitals, who would be responsible for maintaining their stockpiles of necessary items for operational purposes. Hospitals will have an obligation to ensure they have supplies critical to their functioning for certain amount of time. While the Landspítali – University Hospital has already created its preparedness list, smaller hospitals throughout Iceland will also be required to develop and maintain their lists.
- The *third layer* would involve wholesalers and providers, who would maintain a stockpile of critical medicines.

[65] *Regulation on infection prevention control measures (No.817/2012) - Article 7*

Concerns have been raised that mandating wholesalers to keep a three-month security stock could lead to a 15% rise in medicine prices in Iceland due to high costs associated with rotation, resale and storage requirements. To address these challenges, efforts are being made to refine the stockpiling strategy. One of the current key tasks is to define the intended recipients of the stockpile, determine appropriate quantities and establish classification criteria for the equipment. Work is ongoing to finalize the plan, including responsibilities and processes. Additionally, discussions are taking place within the Nordic Council of Ministers about the possibility of having Nordic countries store supplies collectively.

Regarding vaccines targeting the whole population, they are kept at the wholesalers' facilities under a contractual agreement, with ownership managed by the Chief Epidemiologist. Funding for these purchases comes from a specific vaccination budget allocated by the Ministry of Health, which is held in an account managed by the Chief Epidemiologist's office. Iceland procured its COVID-19 vaccines through the EU, in collaboration with Sweden, due to Iceland's non-membership in the EU. Additionally, Iceland has participated in other joint procurements to receive e.g. the Mpox vaccine.

Electronic platform for situational awareness

As member of the Nordic Svalbard Group, Iceland participated in the project Nordic Mechanism for Sharing Situation Awareness in Health and Social Care. It aims to enhance situational awareness by sharing information during crises or threats. Conceptually, the new system has some similarities to the Early Warning and Response System (EWRS) but covers a broader range of preparedness measures. It can address issues such as healthcare staff shortages or any other threats to the healthcare system that need to be communicated. This system also handles requests for information and related matters. While the aim is not to duplicate efforts, the focus is on enhancing information sharing within Nordic countries, given their proximity and similarities. This platform serves more as a discussion forum, reinforcing the tradition of mutual support among the Nordic countries. It formalizes the daily discussions and email exchanges regarding operational matters, such as updates on ongoing issues or requests for assistance happening between the Nordic countries, in a safe platform.

ii. Reports

IMA publishes an annual report on issues such as medical shortages, demand for medicines, pricing and key national and international discussions.

The Directorate of Health maintains a dashboard dedicated to statistics on the use of pharmaceuticals. The full list of public health indicators is published yearly and publicly available.

c. Legislation and strategy

The main laws and regulations related to MCM are listed on the Icelandic Medicines Agency website.

The Medicinal Products Act (No.100/2020, amended in 2024), aims to ensure a sufficient supply of necessary medicines for citizens with patient safety as a guiding principle and with the most efficient distribution of medicines based on normal competition and under the rules that apply in the EEA or according to the founding agreement of the European Free Trade Association.

The Act on Medical Devices (No.132/2020), aims to ensure the quality and safety of medical devices, with public safety as the guiding principle, and to ensure that the production, maintenance and use of medical devices are following the best professional knowledge at any given time. This Act covers the production, importing, distribution, sale, placing on the market, market surveillance, maintenance and use of medical devices and their monitoring. The Act applies both to medical devices with an intended medical purpose and to those without an intended medical purpose.

Regarding preparedness, the Regulation on infection prevention control measures (No.817/2012, amended in 2024), which complements the Act on Health Security and Communicable Diseases (No.19/1997), outlines the protocols and actions for managing communicable disease cases in Iceland. The regulation also addresses the requirement for safety stockpiles of medical products, supervised by the Chief Epidemiologist.

The Civil Protection Act (No.82/2008, last amended in 2025) emphasizes the importance of maintaining adequate stock levels to ensure national survival during emergencies. Specifically, the Act states that the Government's policy on civil protection and security, developed by the Civil Protection Council, should include stock levels necessary to ensure the survival of the nation in times of peril.

Additionally, the Pandemic National Plan (2020) is intended to support the organisation and management of operations in the event of any pandemic. The plan is based on the Civil Protection Act (No.82/2008) and the Act on Health Security and Communicable Diseases (No.19/1997). Specific to MCM, the plan outlines a strategy for the stockpiling and distribution of MCMs to support national preparedness. It includes references to stockpiles of essential medicines, PPE, and vaccines and it highlights the role of IMA in monitoring the availability of drugs and medical supplies, as well as securing additional stock when necessary.

As part of the Svalbard Group, there are multiple working groups, including one for sharing information on medicine shortages. Iceland, as a small market, has long faced challenges with stock issues and lacks the extensive catalogue available to larger markets. The current discussions focus on the establishment of a unified Nordic market, allowing for the interchange of pharmaceutical packages between countries.

Another key task within this group focuses on identifying and addressing legal obstacles that could hinder or delay cross-border assistance among the Nordic countries. This initiative covers a broad spectrum of issues, ranging from legal barriers to the swift deployment of resources, such as the logistical challenge of sending an ambulance from one country to another, to more complex scenarios like responding to medicine shortages during mass casualty incidents.

Additionally, Iceland, Denmark and Norway have established a formal collaboration for joint procurement of medicines, focusing on older, well-known medicines facing supply challenges. This collaboration is utilised for acquiring narrow-spectrum antibiotics, among other medical supplies, particularly for hospitals.

Another priority is to implement an electronic patient information leaflet. During Iceland's presidency of the Northern Council of Ministers in 2019, a request was made to DG SANTE to amend legislation to allow for electronic-only patient information leaflets. This change would enable patients to scan a code on the packaging to access information in their preferred language, rather than relying on printed materials being an added difficulty in marketing drugs due to the requirement of having printed information in Icelandic, which is a rare language with a small market. The current legislative proposal supports this approach. This change could support management in crises, as it eliminates the need for translating printed materials before medicines are shipped to other countries for stock sharing, enabling a more efficient and adaptable response.

Finally, a pilot project conducted by the Nordic Medicines Agencies focuses on the introduction of English-only package leaflets for human medicinal products across Nordic countries. It aims to simplify and standardize product labelling and explore the feasibility and potential benefits of common Nordic packaging that uses only English translations.

VIII. Closing remarks

This report presents the findings of the country visit to Iceland conducted as part of the EU-HIP project. The country visit aimed to gather additional information on the digital systems in place for surveillance and monitoring of PHPP, AMR, CBRN threats, and MCM. The report builds on the initial EU-HIP Deliverable 4.1 *Landscape Analysis* and incorporates insights from the interviews carried out in June 2024.

The purpose of compiling this country-specific material was to give Iceland, as well as the experts developing the ATHINA platform, an overview of the national IT systems currently used for health threat surveillance and medical countermeasures. It also establishes a baseline to support further work within the EU-HIP project and to inform future national and international initiatives.

As part of this process, and in line with Deliverable 5.2 *National Roadmaps to Implementation*, Iceland identified technical needs and translated them into a roadmap for improving national health information systems for preparedness against cross-border health threats.

In parallel with strengthening national capacities, the EU-HIP project also supports the harmonisation of IT systems across EU and EEA countries. The findings from the Iceland country visit will feed into the ongoing development of ATHINA and contribute to broader European efforts to enhance cross-border collaboration in preparedness and response.

ANNEX

Appendix 1 – Internal checklist of the clinical pharmacist at the Poison Information Centre (English translation)

1. Basic Incident Information

- **Location:** Exact address, coordinates, or landmark.
- **Time:** When did the exposure or event occur?
- **Current situation:** Is it ongoing, contained, or resolved?
- **Type of event:** Chemical, Biological, Radiological, Nuclear, or Explosive (or unknown).
- **Who reported it?** First responder, healthcare provider, public health official, or member of the public.

2. Agent or Substance Information

Ask if **any of the following are known or suspected**:

- **Name of the agent or substance** (chemical name, trade name, appearance).
- **Physical form:** Gas, vapor, liquid, powder, solid.
- **Odour, colour, or visible signs:** E.g., chlorine smell, oily droplets, mist, dead animals.
- **Labelling or placards:** From containers, vehicles, or shipping documents (UN number, hazard class).
- **Detection readings:** Results from field detectors or radiation monitors.
- **How was the substance released?** (Explosion, spill, spray, aerosol, contamination of food/water, etc.)

3. Exposure Details

- **Who is exposed:** Number of people, adults/children, first responders, civilians.
- **Route of exposure:** Inhalation, ingestion, dermal, ocular, injection.
- **Duration of exposure:** How long were people exposed?
- **Protective equipment used:** Any PPE or respiratory protection worn?
- **Decontamination:** Has decontamination been done? How (water, soap, bleach, etc.)?

4. Clinical Signs and Symptoms

- **Symptoms reported:**
  - Respiratory (e.g., coughing, shortness of breath)
  - Neurological (e.g., seizures, confusion)
  - Gastrointestinal (e.g., vomiting, diarrhoea)
  - Skin (e.g., burns, blisters, irritation)
  - Ocular (e.g., tearing, blurred vision)
- **Time to symptom onset:** Rapid (seconds–minutes) vs delayed (hours–days).
- **Number of symptomatic vs asymptomatic people.**
- **Any fatalities or severe cases.**

5. Medical and Response Details

- **Where are patients being treated?** (Hospitals, field triage, etc.)

- **Treatment given so far:** Oxygen, antidotes (e.g., atropine, pralidoxime), supportive care.
- **Need for antidotes or specialized equipment.**
- **Availability of critical care capacity nearby.**
- **Any unusual resistance to treatment.**

6. Safety and Containment

- **Scene safety:** Is the area secured or still hazardous?
- **Decontamination site location and procedures.**
- **Environmental contamination:** Water, air, soil, or building affected?
- **Evacuations or shelter-in-place orders in effect?**
- **Responder safety:** Any first responders affected?

7. Coordination and Communication

- **Other agencies involved:** Fire, police, HAZMAT, public health, environmental authorities, hospitals.
- **Contact person and call-back number.**
- **Information shared with national health or emergency management agencies.**

8. For Unknown or Unconfirmed Events

If the caller is unsure what the agent is:

- Ask about **patterns** of illness or injury (e.g., sudden collapse, seizures, pinpoint pupils).
- Ask about **environmental clues** (e.g., fog, mist, dead animals, metallic taste).
- Encourage **preservation of samples** (environmental and biological) if safe.
- Emphasize **safety, PPE use, and decontamination** before further assessment.

Summary for Rapid Triage (Mnemonic)

A useful quick reference for poison information staff is the **"5Ws + H"**:

- **Who** is affected?
- **What** agent or exposure?
- **When** did it happen?
- **Where** did it occur?
- **Why/How** did exposure occur?
- **How severe** are the effects?