



PORTFOLIO

Institute of Public Health of the
Republic of North Macedonia



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**INSTITUTE OF PUBLIC HEALTH OF
THE REPUBLIC OF NORTH MACEDONIA**

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на Република Северна Македонија

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LEGAL IDENTITY

The Institute of Public Health of the Republic of North Macedonia (referred to as IPH RNM) is registered as Public Health Institution in the Central Registry of the Republic of North Macedonia by Decision of 2 November, 2009. The legal acts, the Statute and Rulebook for internal organization and systematization of workplaces regulate the organization, tasks, authorizations, mutual relationship and responsibilities of employees.

ABOUT THE INSTITUTE

The representativity of the public health care segment in the state nowadays, through the activities of the Institute of Public Health and the 10 regional Institutes, is significant with the sensible and realized quantum of expert opinions, supervisions and control, analytical observations and risk estimation, in the creation of the particularities from the field/terrain peculiarities as an individual picture, until their collective analysis as a general picture.

The past period represented the pinnacle of serious activities in the creation of the contemporary system of preventive medical protection as a basic managing instrument by defining priority problems and taking on suitable solutions on national, regional and local level. A categorical imperative in the implementation of the national strategy and the public health is improving the population health in the of the Republic of North Macedonia by improving the components of health and stimulating all those that directly or indirectly influence the current situation.

HISTORY

The institutionalization of preventive activity in North Macedonia began in the twenties of the last century. In 1921, the first Bacteriological Station in Skopje was established (Decree on the Establishment of a Bacteriological Station, No. 29.964 of 1920).

The existing documents, though not so precise, lead to the conclusion that exactly in May 1924 the Institute for Tropical Diseases was founded from the Bacteriological Station with a laboratory for examination of tropical diseases in Skopje under the auspices of Dr. Andrija Stampar and with the participation of The Rockefeller Foundation in Skopje, whose function was to protect and improve people's health.

This medical institution of preventive character operated in conditions when infectious diseases were the main feature of the national pathology in that period. From the middle of 1927, the title Institute of Hygiene Skopje appeared in the official correspondence. From 1941 to 1945, it functioned under the name Authorized Institute of Hygiene in Skopje.

As of 1947, the Institute of Hygiene in Skopje functioned under the name Bacteriological and Chemical Institute under the patronage of the Ministry of Public Health. From 1953, the Institute functioned as the Central Hygiene Institute. On 15.02.1962 with act no. 02-2515 the Institution was registered as the Republic Institute of Health Care - Skopje. Under this name, the Institution functioned until 2 November 2009, when it was registered in the Central Registry of the Republic of Macedonia as PUBLIC HEALTH INSTITUTION - INSTITUTE OF PUBLIC HEALTH OF THE REPUBLIC OF MACEDONIA.

MISSION

To promote health and general welfare of the population through knowledge-based science, best practices, information and organizational partnerships and impact on sustainable public health policies.

VISION

Healthy population in a healthy and safe living environment, sustainable health system and security from global and local public health threats.

OUR VALUES

Quality - We upgrade the quality by providing appropriate/adequate level of excellence in providing services based on a high level of knowledge, expertise of our scientific and professional staff as well as by implementation of internationally accredited methods and laboratories.

Tradition - We are proud of our long-standing tradition as it is rooted in the realization of our activities as a moral obligation of the employees in order to justify the confidence gained from users and partners.

Efficiency - In the realization of the activity we are guided by the justification of the investments and funds we have spent by using proofs, scientific facts and best practices for the achievement of optimal results.

Partnership - Our work is based on building partnerships and cooperation with our long-term partners in the country and abroad on the basis of mutual trust.

Responsibility - Based on the principle of fairness and human dignity, we feel responsible for the health and welfare of the whole population in the Republic of North Macedonia.

PRINCIPLES OF PUBLIC HEALTH

Public health is a system of knowledge and skills for preventing diseases, prolonging life and promoting health by the organized efforts of the society.

The Institute of Public Health of the Republic of North Macedonia in accordance with the Law on Health Care and the Law on Public Health and as a national health institution is on the first line in the realization of this goal. Ensuring an appropriate level of excellence in the process of providing its services, based on the highest level of knowledge available and applicable in the Republic of North Macedonia, is based on the principles of:

1. Responsibility for the health of entire community and the leading role of the country in preserving and improving population's health;
2. Comprehensiveness of measures and activities focusing on the entire population and on separate social groups as well as on socioeconomic determinants of health and the most important risk factors;
3. Intersectoral cooperation, multidisciplinary and interdisciplinary approach to health promotion, which is achieved by continuous improvement of cooperation with health institutions involved in public health and with other participants in public health;
4. Scientific basis and comprehensives in collecting data using quantitative and qualitative methods, which means activity of public health based on scientifically proved and tested methods and procedures used to promote and preserve the population's health;
5. Partnership with the population and strengthening civil initiatives in the field of public health, realized by raising awareness about the importance of care for our own health;
6. Efficiency and effectiveness of public health are realized by achieving the best possible results depending on the available financial resources, that is, achieving the highest possible health level with the lowest expenditure of resources.

ORGANIZATION

Regarding maintenance and promotion of health as well as prevention of diseases and health-related problems, the IPH as part of the public health is facing challenges in implementing world reference standards and continuous monitoring and training for using modern analytical and diagnostic procedures along with new trends in medical sciences, social sciences and humanities.

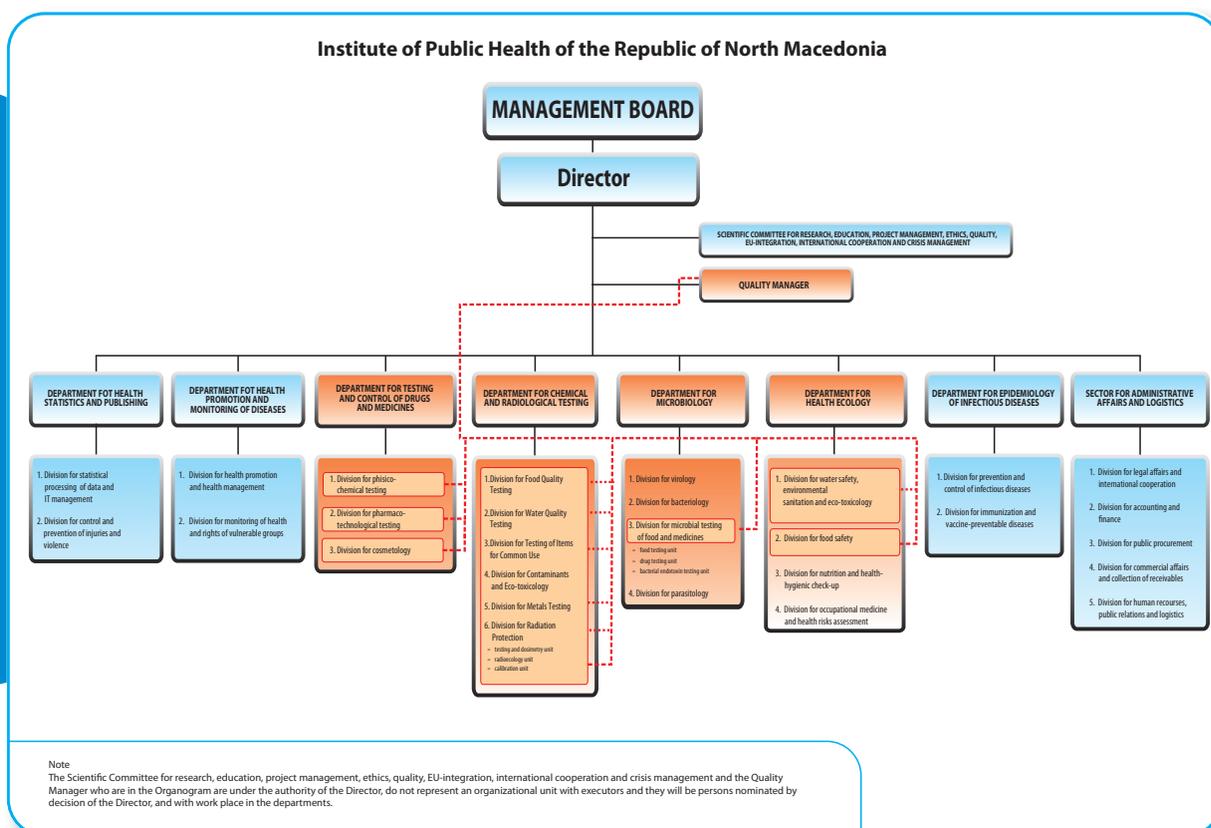
In our institution, this is realized with maximum commitment and effort, enthusiasm, creativity and professionalism of all actors and all professionals involved in public health activity.

In order to achieve its goals and in line with its Statute, the IPH is organized in 7 departments and 1 sector with two or more departments while the scientific board and the quality manager represent separate entities.

The Institution is managed by a director, and the work of the Institution is under the supervision of the Management Board (see Organogram).

As of June 30, 2022, the Institute of Public Health have 202 regular employees from various profiles: doctors of medicine, pharmacists, doctors of dental medicine, food technology engineers, chemical engineers, mechanical engineers, physicists, nuclear physicists, biologists, biochemists, technologists, nurses, laboratory technicians, pharmaceutical technicians, etc.

Among the employed in the Institute there are professors, assistant professors, assistants, doctors of science in public health, doctors of science in medical and non-medical scientific fields, masters in public health and other scientific fields, then graduate employees with completed three-year professional studies, but also with completed specializations, as well as economists, lawyers, etc.





J.З.У. ИНСТИТУТ ЗА ЈАВНО ЗДРАВЈЕ НА РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА
I.S.H.P. INSTITUTI I SHËNDETIT PUBLIK I REPUBLIKËS SË MAQEDONISË SË VERIUT
INSTITUTE FOR PUBLIC HEALTH OF THE REPUBLIC OF NORTH MACEDONIA

QUALITY POLICY

The Institute of Public Health of RNM (PHI IPH), as an institution with many years of experience in the healthcare industry is permanently determined to maintain high standards and quality in all its activities and to continuously improve its reputation and respectability. We achieve this goal by applying the quality policy, which obliges us to an appropriate organization of work, assigning powers and responsibilities that will ensure good professional practice and will allow maintaining high standards of service quality in all areas of work. All activities in PHI IPH are carried out in an unbiased, independent, objective and confidential manner.

The main goal of the established quality system is to satisfy the requirements of the regulations and other normative documents as well as the requirements of the users, which is reflected by issuing accurate and quality test results, as well as meeting deadlines and timely performance of activities. All employees of PHI IPH are included in the documented management system, they use procedures and work instructions that they consistently implement in their work. The management of PHI IPH emphasizes its dedication and commitment to development, and each of the employees, pursuant to their own powers/authorizations and responsibilities, contributes to improving the effectiveness of the institutions work. The application of ISO/IEC 17025:2017 ensures continuous improvement of the quality system and the provision of an appropriate framework for the establishment and review of realistic and measurable quality objectives.

The quality policy of PHI Institute of Public Health of RNM is based on:

- Ensuring a high level of service for our users and minimizing complaints and grievances.
- Availability of appropriately qualified personnel by providing continuous training for its employees to ensure they possess the necessary skills to properly perform and maintain work activities.
- Ensuring impartiality, confidentiality and absence of conflict of interest. The personnel involved in testing and calibrations are freed from any unacceptable internal and external pressures, commercial, financial and other influences that may negatively affect the quality of their work and decision-making. The integrity of the test results is the responsibility of all engaged personnel.
- Access to appropriate resources, infrastructure, equipment and materials that are needed to perform the assigned tasks.
- Implementing effective controls to monitor work processes and identifying risks and opportunities for improvement.
- Successful regular participation in programs of interlaboratory comparisons and proficiency tests for all testing and calibrations within the scope of accreditation.
- Cooperation with related relevant laboratories at the national and international level

Skopje, 6.5.2022

DIRECTOR,
Assoc. Dr. Shaban Memeti

QUALITY POLICY

The Institute of Public Health of the Republic of North Macedonia (PHI IPH) as an institution with long-standing experience in health care, is permanently determined to maintain high standards and quality in all its activities and continuously improve its reputation and respectability. We accomplish our mission by applying a defined quality policy, which obliges us to an appropriate organization of the work, assignment of authorizations and responsibilities that will ensure good professional practice and will enable maintaining high standards of service quality in all areas of work. All activities in PHI IPH are carried out in an unbiased, independent, objective and confidential manner.

ACCREDITATION AND CERTIFICATION

Recognizing the importance of application of the quality standards in its activity/work, PHI IPH started to implement them a long time ago. The laboratories within PHI IPH, which are part of the Center for Reference Laboratories, were among the first in Macedonia to be accredited according to the requirements of the ISO 17025:2006 standard. The first certificate for accreditation of laboratories regarding testing and calibration according to ISO 17025:2006, PHI IPH received on 25.12.2006, awarded by the Accreditation Institute of the Republic of Macedonia. Since then, the PHI IPH has regularly improved its work and has followed the new requirements for quality procurement in the work, which is also confirmed on the basis of regular annual inspections by the Accreditation Institute of the Republic of North Macedonia. The laboratories' expertise and competence are also confirmed by regular successful participation in competencies testing schemes and inter-laboratory comparisons in the country and abroad.

The main purpose of the established quality system is to satisfy the requirements of the regulations and other normative documents as well as to meet the requirements of the users of services, which is reflected by issuing accurate and high-quality test results, as well as compliance with deadlines and timely performance of activities. All employees of PHI IPH are acquainted with the quality policy and are included in the document management system; they use procedures and work instructions that they consistently implement in their work. A representative appointed by the management - Quality Manager - is responsible for the proper functioning of the certified quality system. In this way, the management of PHI IPH emphasizes its dedication and commitment to development, and each of the employees, in line with her/his own powers and responsibilities, contributes to improving the effectiveness of the institution's work.

The Institute of Public Health strives to follow the world's achievements in the field of analytics and to be always prepared to respond to the requests and needs of the users of services and inspection bodies. The testing laboratories that function within the Department of Chemical and Radiological Testing, the Department of Microbiology and the Department of Testing and Quality Control of Drugs in PHI IPH are accredited for food testing (quality and safety - microbiology, pesticides, heavy metals, mycotoxins, radiology), drinking water, mineral water and surface water (quality and safety, content of gamma-radionuclides, alpha and beta activity), soil and atmospheric sediments, building materials, medicines and items of general use (toys, plastic objects and ceramics) and materials that come into contact with food. The calibration laboratory is accredited for the calibration of instruments for detection of ionizing radiation.

The scope of accreditation includes about 100 test methods and 4 calibration methods; the list of methods accredited according to laboratories can be found on the website of the Accreditation Institute of R.N. Macedonia (LT-005 and LK-008).



MANAGEMENT TEAM

DIRECTOR:

Assoc. Prof. Shaban Memeti, MD, PhD

MANAGERS:

Prof. Elena Kjosevska, MD, PhD

Prof. Mihail Kochubovski, MD, PhD

Prof. Zorica Arsova Sarafinovska, PhD

Prim. Gordana Kuzmanovska, MD

Prim. Vjosa Recica, MD

Katerina Starkoska, grad. pharm. spec

Dugagin Osmani, MD, spec. microbiol

Juliana Tomanovska, grad. econ.

Subsidiary bodies, which are not organizational units, have also been established at the Institute:

SCIENTIFIC COMMITTEE FOR RESEARCH, EDUCATION, PROJECT MANAGEMENT, ETHICS, QUALITY, EU-INTEGRATION, INTERNATIONAL COOPERATION AND CRISIS MANAGEMENT

QUALITY MANAGER

Maja Dimitrovska, Eng., PhD

MANAGEMENT BOARD

Prof. Gordana Ristovska, MD, PhD, president

Zana Mustafa, MSc, member

Susana Subasic, MD, member and deputy president

Elena Shishkovska, MD, member

Njomza Limani Bakiyi, MD, member

ACTIVITY OF THE INSTITUTE

The main ACTIVITY of the Institute of Public Health is CARE FOR THE POPULATION HEALTH via monitoring, research and study of the health condition, the causes for the emergence and spread of infectious and non-infectious diseases of epidemiological and social-medical importance, the impact of environmental factors and taking on measures for protecting and improving people's health.

The activity of the IPH defined in the Law on Health Care, the Law on Public Health, the National Annual Program for Public Health and other legal acts and by-laws is carried out by implementation of scientific, professional and educational activities, i.e., implementation of 4 key health activities:

1. social-medical activity
2. epidemiological activity
3. sanitary hygiene activity
4. microbiological activity

In its activity, the Institute also performs the following tasks:

- ✧ Provides expert assistance to the Ministry of Health in the preparation of medium and long-term plans and programs for public health in the area of health protection and promotion, population screening, monitoring and control of infectious and non-infectious diseases;
- ✧ Coordinates, controls and professionally and methodologically supports the accomplishment of the preventive program tasks of the Public Health Centers and their regional units;
- ✧ Implements and coordinates public health measures in case of epidemics, natural disasters, and other crises, emergencies and disasters across the territory of the Republic of North Macedonia in cooperation with other institutions;
- ✧ Conducts scientific research in the field of public health for evaluation of the outcome and impact of preventive programs in order to bring evidence-based policies;
- ✧ Participates in the realization of scientific research projects in the field of hygiene and health ecology, epidemiology, microbiology, social medicine, that is, in the field of preventive domain;
- ✧ Has international cooperation with related institutions in the field of public health and provides data on health condition to international organizations in accordance with the law;
- ✧ Collects, processes and analyzes data on diseases and mortality of the population and other data on the health condition of the population, on the hygienic-epidemiological conditions, on infectious and non-infectious diseases, as well as on other environmental

conditions that have an impact on the population health status;

- ✧ Proposes and participates in the implementation of unique programs for health education in cooperation with other health institutions, implements activities for health promotion and diseases prevention;
- ✧ Conducts national and international behavioral studies on citizens' lifestyle and health behaviors;
- ✧ Monitors, studies, analyzes and evaluates the epidemiological situation with regards to infectious diseases and deals with current problems related to infectious diseases and crisis situations;
- ✧ Monitors the realization of immunization, collects, processes and analyzes data on population vaccination coverage and proposes measures to improve conditions related to immunization and its coverage;
- ✧ Prepares strategic documents, proposes and implements doctrinal policies, proposes/participates in drafting legal regulations and by-laws regarding infectious diseases and immunization;
- ✧ Estimates the health and environmental risks of air pollution, food, items for general use, drinking water, bathing water, waste water and solid waste, with a particular aspect on medical waste, and also participates in preventive sanitary supervision over the building of civil and other facilities, uses modern software tools for risk assessment related to health ecology;
- ✧ Monitors, i.e., implements measures for active protection of the population, as well as of diseases and conditions resulting from inadequate nutrition and proposes measures for their elimination;
- ✧ Participates in preparation of legal acts and by-laws, prepares reports and expert opinions in the field of health ecology, food safety, nutrition and occupational medicine;
- ✧ Performs microbiological (bacteriological, virological, parasitological) analysis, analysis of pesticide residues, radiological, contaminants, mycotoxins, and also, toxicological and biochemical and other laboratory analyses in the framework of its activity, then monitors ionizing radiation in the environment and performs biodosimetry;
- ✧ Projects the development and organizes the work of the information system in the field of healthcare;
- ✧ Performs examination and control of finished medicines/drugs, active pharmaceutical substances and herbal preparations; laboratory control and superanalysis of narcotic drugs and psychotropic substances; examination of raw materials and products for cosmetics and hygiene products;
- ✧ Participates in the educational activity on the level of undergraduate, postgraduate and doctoral studies, as well as specializations in the field of hygiene and health ecology, occupational medicine, epidemiology and social medicine; and conducts activities related to professional development of health workers and health associates from the preventive field;

- ★ The Institute of Public Health is a teaching base of the Faculty of Medicine and Faculty of Dentistry at Ss. Cyril and Methodius University in Skopje, and some of the teachers participate in the teaching process at other universities in the country (Goce Delchev University in Shtip and the State University in Tetovo), as well as abroad.
- ★ As an institution that carries out tertiary specialized preventive activity, the Institute of Public Health coordinates the tasks arising from the legal regulation in cooperation with the 10 Centers for Public Health, the Ministry of Health, the Ministry of Environment and Spatial Planning, the Ministry of Labor and Social Policy, the Ministry of Education and Science, the Ministry of Internal Affairs, institutes and other health institutions from public and private health, local self-government, non-governmental organizations, businessmen, manufacturers, trading companies, and other entities that for various reasons are close to the activity performed by this institution.
- ★ The professional activity of the IPH is the basis for creating the national policy in the field of public health, bearing in mind that the experts employed at the Institute are some of the creators of many legal acts and by-laws, national strategies and action plans, preventive programs, etc., but with their expertise, they are also creators of international health policy as contact persons and/or national collaborators with the World Health Organization (WHO), the European Center for Disease Prevention and Control (ECDC), UNICEF, UNFPA, UNDP, the World Bank, Council of Europe, IAEA, etc.
- ★ The Institute of Public Health is an organization that is included in many international organizations: IANPHI, BENA, SHE, EMCDDA, FAO, etc. The cooperation of the Institute of Public Health with these organizations is of benefit to the population of North Macedonia because preventive health care is a postulate for a healthy and long life.

FINANCING

The financing of the activities of the Institute is provided out by realization of the program activities anticipated in the government preventive programs, from services to citizens and patients from the laboratory activity based on an agreement with the Health Insurance Fund of the RSM, funds that are provided by donations for research projects, other funds provided by the services that the Institute performs for manufacturers, importers and exporters of medicines, food, items for general use, as well as other services resulting from the professional competencies of the Institute's employees.



SPECIAL SECTION

ACTIVITIES OF SEPARATE DEPARTMENTS AND ONE SECTOR

A) Social-medical activity

1. DEPARTMENT FOR HEALTH PROMOTION AND MONITORING OF DISEASES

Head: Prof. Elena Kjosevska, MD, PhD

Activities of the Department for Health Promotion and Monitoring of Diseases:

- ★ plans, coordinates, implements and evaluates activities for health promotion and diseases prevention,
- ★ monitors the health status of the population, the system, the organization and financing of health care,
- ★ participates in preparation and implementation of special programs from health activity,
- ★ proposes measures to address the health needs of the population,
- ★ determines priorities to meet the needs and improve the health status of the population,
- ★ provides professional expertise for creation of evidence-based public health policy,
- ★ participates in preparation of national laws in the field of health, national and international strategies, action plans, standards and norms, public health preventive programs as well as national and international indicators for monitoring and evaluation of the health condition and health care of vulnerable groups of the population,
- ★ carries out publishing activity by issuing publications and health-educational materials (brochures, posters, leaflets etc.),
- ★ implements/conducts scientific research projects in the field of health,

- ★ cooperates with national and international institutions from the country and abroad,
- ★ conducts teaching and educational activities in the field of social medicine and public health,
- ★ provides expert-methodological assistance to health organizations in the field of social medicine, health education and economics in health.

Divisions in the department:

- ★ Division for Health Promotion and Health Management
- ★ Division for Monitoring of Health and Rights of Vulnerable Groups

Division for Health Promotion and Health Management

- ★ implements/performs health-educational activities by development of global and specific national programs for health education;
- ★ organizes and implements/carries out health promotion campaigns, educational workshops, forums, and other types of manifestations;
- ★ monitors the realization and evaluation of the results;
- ★ cooperates with international organizations with an aim to carry out activities related to health promotion;
- ★ provides expert-methodological assistance where needed;
- ★ participates in the educational activity and education of health personnel of all profiles in the field of health education;
- ★ directly cooperates with the means of public information, humanitarian organizations, associations and organizations from the country and abroad;
- ★ carries out publishing activity by issuing publications and health-educational materials (brochures, posters, leaflets, etc.);
- ★ conducts scientific-researcher projects in the field of health care;
- ★ monitors and studies the financing system of health activity and proposes measures for its improvement;
- ★ performs analysis of the material and financial situation of the health care (the Healthcare Insurance Fund and healthcare organizations);
- ★ analyzes health care expenditures in the public and private sector per activity;
- ★ monitors and analyzes the cost of individual health services defined by the basic package of services;
- ★ monitors and analyzes health indicators for health care expenditures;
- ★ evaluates the functional activity and health service utilization;
- ★ selects, prepares, and analyzes demographic and other indicators for assessing the needs and requirements of the population for certain types of health care (defined population groups);
- ★ participates in the improvement of the methodology and selection of data for the economic analysis of the population health care
- ★ participates in the preparation and implementation of professional and scientific projects related to organization, economy and informatics in health care;
- ★ provides expert-methodological assistance to healthcare organizations in the field of social medicine and health care economics;

- ★ carries out education and professional development/training of medical and other personnel of different profiles in the field of health care economics.

Division for Monitoring of Health and Rights of Vulnerable Groups

- ★ participates in preparation and implementation of special programs for the control of non-communicable diseases;
- ★ determines priorities to meet the needs and improve the situation with non-communicable diseases of the population;
- ★ provides qualitative, valid and up-to-date data about the state of non-communicable diseases;
- ★ proposes measures to address the health needs of the population suffering from chronic non-communicable diseases;
- ★ performs scientific research activity with an aim to assess/evaluate the risk of the occurrence of non-communicable diseases at the local, regional and national levels;
- ★ prepares educational and promotional materials for prevention of non-communicable diseases of the population in all settings for the general public and mass media;
- ★ carries out publishing activity by producing publications - information, reports, analyses and printing of health and educational materials (brochures, posters, leaflets, etc.);
- ★ participates in educational activity and education of health personnel of all profiles;
- ★ cooperates with state and international institutions by participation in joint projects and other types of activities (participation in working groups, commissions, etc.)
- ★ monitors the health condition of all vulnerable groups (children, women, adolescents, youth, people with disabilities, migrants and the elderly);
- ★ proposes measures to address the health needs of vulnerable groups;
- ★ carries out scientific-research activity aimed at assessing the risk of diseases outbreaks of individual vulnerable groups at local, regional and national levels;
- ★ conducts site visits in order to make expert-methodological assessment of preventive teams and vaccination points in the Republic of North Macedonia;
- ★ conducts health-educational activity and education of families in rural areas and Roma communities about children's health, vaccinations, safe motherhood, and adolescent health;
- ★ prepares, prints/publishes and distributes guidelines for health workers and brochures for parents;
- ★ cooperates with state and international institutions through joint projects and other activities (participation in working groups, commissions, etc.).



2. DEPARTMENT FOR HEALTH STATISTICS AND PUBLISHING

Head: Prim. Vjosa Recica, MD

Activities of the Department for Health Statistics and Publishing:

- ★ conducts health-statistical activity through collecting, control, and computer processing of health-statistical data
- ★ applying data software analyses, the Department manages and publishes the national registers “Cancer Registry in the Republic of North Macedonia”, and “Diabetes Registry in the Republic of North Macedonia”, prepares publications for patients treated in primary health care, “Outpatient Polyclinic Morbidity in North Macedonia” and for the inpatient treated persons in the hospital departments “Hospital Morbidity and Mortality in the Republic of North Macedonia”;
- ★ prepares precise records of healthcare personnel using a well-established computer database;
- ★ cooperates with state and international institutions and organizations (such as WHO, EUROSTAD, EU, etc.) so as to monitor and apply the innovations in its activity;
- ★ monitors the statistical processing of reports on the work of health organizations;
- ★ participates in the preparation of programs for statistical research in the field of healthcare;
- ★ participates in preparation of professional and methodological guidelines for conducting statistical investigations in the field of health;
- ★ prepares national health indicators;
- ★ participates in preparation of forms for medical documentation, records and reports;
- ★ performs expert supervision in the field of health statistics in health organizations;
- ★ coordinates the professional work in the field of health statistics in the health care institutes and regional services of the institutes;
- ★ participates in creation of projects for the health information system in the Republic;
- ★ participates in creation of operational plans for the introduction of application programs;
- ★ performs analysis and evaluation of statistical data;

- ★ participates in educational activity and conducts activities related to professional development of health workers and associates of various profiles during internship and specialist training as well as other types of professional development in the field of health statistics;
- ★ carries out educational activities regarding professional development of medical personnel from different profiles in the field of health statistics, health informatics and electronic data processing by organizing courses and seminars, as well as field/site insights in health organizations with expert-methodological assistance and instruction.

Divisions in the Department:

- ★ Division for Statistical Processing of Data and IT Management
- ★ Division for Control and Prevention of Injuries and Violence

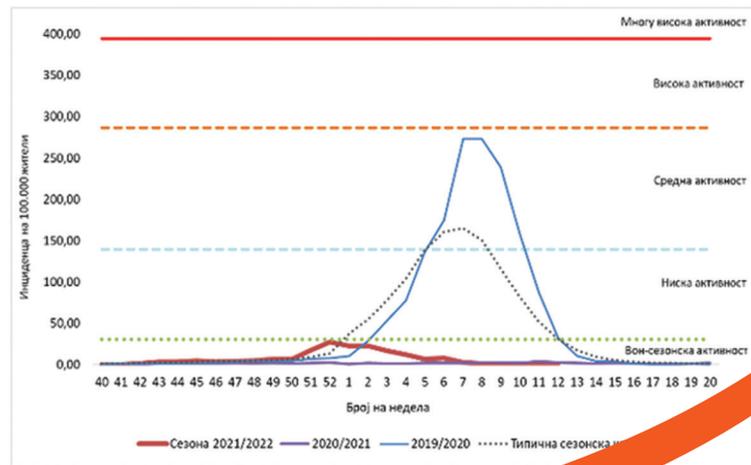
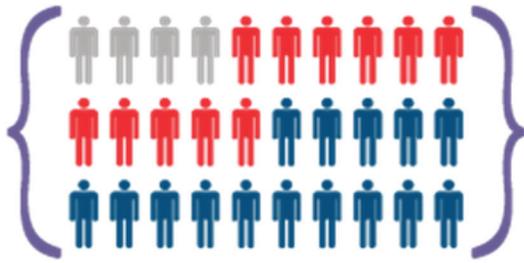
Division for Statistical Processing of Data and IT Management

- ★ preparation of programming tasks and programs for using databases;
- ★ analyzing software solutions aiming at improvement of designing and programming;
- ★ updating and completing program documentation for electronic processing and optimal use of data;
- ★ adding/building up and improving health information system (IS);
- ★ cooperation with the users during the installation and construction of IS;
- ★ creation of the layout of the output information and preparation of system analyses;
- ★ creation guidelines for preparation and coverage of data through IS;
- ★ monitoring and analyzing the functioning of IS;
- ★ administration and maintenance of the operating systems, databases and application software solutions used by IPH;
- ★ administration and maintenance of application software solutions;
- ★ maintenance of the computer network in IPH and all other external communication links;
- ★ ensuring secure/safe and timely archiving of data;
- ★ administration and maintenance of data security systems from unauthorized access and use that are of IPH interest;
- ★ administration and maintenance of virus protection system of the information system of IPH;
- ★ taking care of the correct use and functioning of the infrastructure required for the functioning of the computer equipment (power supply, PP protection, air conditioning, movement control in the system hall);
- ★ preparation of publications, information brochures, analyses and other materials through in-design in PDF format for the needs of the Center for statistical processing of health data, publishing and education as well as for the needs of all sectors in the IPH of RNM and the Ministry of Health of the Republic of North Macedonia;

- ★ technical maintenance of computer and other technology (computers, printers, scanners, audio and video and other technical equipment) used in IPH and maintenance of the computer network;
- ★ carrying out evaluation of archival material and preparing the register of archival material;
- ★ preparation of the plan of archival signs and the list of archival materials of permanent value;
- ★ storing and handling of archival samples in accordance with the law on archival materials and by-laws;
- ★ registering of the documentary material and its preparation for storage and annulment;
- ★ implementing measures to protect archival and documentary materials from physical and chemical damage;
- ★ systematized arrangement of the archival material for handing it over to the State Archive of the Republic of North Macedonia.

Division for Control and Prevention of Injuries and Violence

- ★ monitors and studies the situation with injuries and violence at local, national, regional and global levels;
- ★ monitors and studies risk factors for injuries and violence;
- ★ prepares injuries registers according to current legislation and EU standards
- ★ participates in designing a national information system for monitoring injuries according to WHO recommendations;
- ★ prepares reports, analyses and expert opinions on safety, i.e., situation with injuries and violence;
- ★ prepares national programs for the control and prevention of injuries and violence;
- ★ participates in creating the national strategy and action plan for the control and prevention of injuries and violence;
- ★ suggests appropriate measures for the organization of the health service for the control and prevention of injuries: pre-hospital care, transport of the injured, hospital care, treatment and rehabilitation of the injured;
- ★ performs analysis of the social-medical aspects of injuries and violence as well as economic analyses of certain intervention programs for the control and prevention of injuries and violence;
- ★ performs health educational activities and other activities for the promotion of safety in the community;
- ★ prepares educational and promotional materials for the safety of all structures in all environments from all injuries for the general public and mass media.



B) Epidemiological activity

3. DEPARTMENT FOR EPIDEMIOLOGY OF INFECTIOUS DISEASES

Head: Prim. Gordana Kuzmanovska, MD

Activities of the Department for Epidemiology of Infectious Diseases:

Epidemiological activity in the Republic of North Macedonia is carried out on the basis of the Law on Public Health, the Law on Health Protection, the Law on the Protection of the Population from Infectious Diseases, by-laws from this area as well as on the basis of the annual programs adopted by the Government of the Republic of North Macedonia.

According to the mentioned legislation, the recommendations of the global policy “Health for all” and the policy “21 goals for the 21st century” and further evaluation of the National Annual Program for Public Health in the Republic of North Macedonia, in the future period it is necessary to significantly reduce the negative effects of certain infectious diseases on the population health and to ensure control, elimination and eradication of those infectious diseases.

In the context of the commitments of the Republic of North Macedonia for integration into the European Union, in the future period the epidemiological activity will continue with its activities aimed at harmonizing with the legal regulations of the European Community.

Priority goals from the field of epidemiology are:

1. Maintenance of the results achieved by the eradication of polio;
2. Elimination of tetanus in newborns;
3. Elimination of indigenous smallpox and rubella and prevention of congenital rubella infection (CRI);
4. Continued, enhanced monitoring of mandatory immunization of all girls aged 12 against HPV infection;
5. Control of other diseases against which mandatory immunization is carried out;

6. Reduction of high morbidity from enterocolitis in young children, from viral hepatitis A, salmonellosis and other intestinal infectious diseases;
7. Reduction of morbidity from other viral hepatitis B and C for the prevention of hepatocellular carcinoma;
8. Reducing the risk of introducing and spreading malaria and other vector-borne diseases (West Nile fever, dengue);
9. Reducing the risk of introducing and spreading cholera and other tropical and quarantine diseases;
10. Reducing the incidence of brucellosis and other zoonoses, preventing their epidemic occurrence;
11. Prevention of naturally focal infections;
12. Prevention of HIV/AIDS and other sexually transmitted infections;
13. Prevention and suppression of intrahospital infections;
14. Monitoring and surveillance of influenza and influenza-like illnesses as well as other acute respiratory illnesses;
15. Prevention and suppression of infectious diseases of greater epidemiological and social importance such as emergence of cases of new infectious diseases, reoccurring diseases and outbreaks of infectious diseases.

In accordance with the above-mentioned acts, the Department implements the following measures and activities:

- ★ Monitoring, studying, analysis and evaluation of epidemiological situation, dealing with current problems related to infectious diseases in specific areas and the Republic as a whole.
- ★ Collecting, processing and analyzing the reports on infectious diseases/causing agents of infectious diseases and epidemiological surveys, field epidemiological insights and information on the conditions on the ground, recommending measures and activities for the prevention and suppression of infectious diseases and control over their implementation.
- ★ Preparation of seven-day reports, monthly bulletins with epidemiological commentary, annual reports and information, periodical reports and analyses of the condition and movement of infectious diseases and the measures taken for their prevention and suppression.
- ★ Preparation of draft national Programs in the field of interest, operational plans, protocols and professional guidelines for the prevention and suppression of infectious diseases.
- ★ Preparation of operational plans in the event of an increased number of infectious diseases or an epidemic with anti-epidemic measures and activities for the entire health activity.
- ★ Implementation of measures and activities for the prevention and suppression/elimination of intrahospital infections.
- ★ Monitoring and control of the performed prophylactic disinfection, disinsection and deratization according to epidemiological indications.

- ★ Preparation of the annual Immunization Draft Program and monitoring its implementation and coverage, providing expert-methodological assistance in the preparation of annual operational plans, organization, implementation, monitoring as well as evaluation of mandatory immunization and preparation of reports on performed immunization and coverage.
- ★ Participation in the work of professional bodies at the Ministry of Health related to prevention, prevention and suppression of infectious diseases as well as immunization (Commission on Infectious Diseases, Commission on Influenza, Commission on Tuberculosis, Committee on Immunization, and others).
- ★ Cooperation with international institutions, organizations and bodies that deal with the problem of infectious diseases and immunization (WHO, ECDC, CDC).

Divisions in the Department:

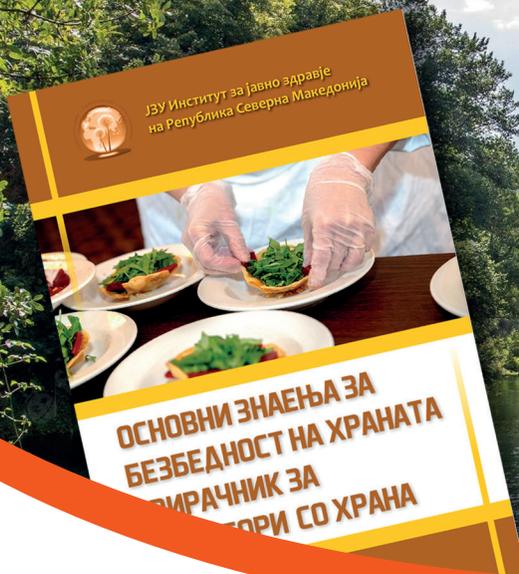
- ★ Division for Prevention and Control of Infectious Diseases
- ★ Division for Immunization and Vaccine-Preventable Diseases

Division for Prevention and Control of Infectious Diseases

- ★ Monitoring and control over infectious diseases in North Macedonia by collecting, analyzing and processing individual reports on infectious diseases, reports on microbiologically proven causes of infectious diseases, group (seven-day) reports on influenza as well as numerous pieces of information, notices and other facts/data on the development of infectious diseases, which it receives from the regional Centers for Public Health and their regional units as well as other health institutions;
- ★ Proposing, undertaking and controlling the implementation of measures for the prevention and suppression/elimination of infectious diseases;
- ★ Participation in field epidemiological research in the Republic and providing expert-methodological assistance;
- ★ Preparation of weekly, monthly and annual reports on infectious diseases movement in the Republic of North Macedonia, with epidemiological commentary;
- ★ Monitoring the situation with zoonoses in the Republic and performing coordinated activities to bring them under control in cooperation with the Food and Veterinary Agency, especially brucellosis as a zoonosis that is a subject to special program-regulated measures and activities for prevention;
- ★ Preparation of draft annual programs (for public health, brucellosis and immunization) and (their) submission to the Ministry of Health;
- ★ Preparation of annual reports on the realization of the mentioned preventive programs, annual report on the movement of infectious diseases in the Republic as well as annual reports on the accomplished work/activities of the Department.

Division for Immunization and Vaccine-Preventable Diseases

- ★ Monitoring and control over the implementation of mandatory immunization in the Republic (according to the Vaccination Calendar), through regular site controls and coverage reports, while providing expert methodological assistance to immunization services and regional/local epidemiological services (pointing out omissions/drawbacks and proposing measures for their elimination, recording and reporting);
- ★ Preparation of periodical information, semi-annual and annual report on the implementation of mandatory immunization in North Macedonia with the achieved coverage and proposed measures to improve the coverage.



C) Sanitary and hygiene activity

4. DEPARTMENT FOR HEALTH ECOLOGY

Head: Prof. Mihail Kochubovski, MD, PhD

Activities of the Department for Health Ecology:

- ★ Coordination, expert/professional control and supervision of the work of sanitary and hygiene activities in 10 Centers for Public Health in the Republic of North Macedonia;
- ★ Preparation and implementation of strategic documents and action plans in the field of health ecology, food safety and nutrition;
- ★ Coordination of activities for drafting national regulations in compliance with international regulations/standards in the field of health ecology;
- ★ Preparation of doctrinal attitudes in the methodological approach and evaluation of the implemented measures and activities in the sanitary-hygienic activity;
- ★ Based on conducted research and data obtained from the Public Health Centers, this Department monitors and evaluates the health-environmental risk of certain factors in the environment;
- ★ The Department participates both in the program segment of the Institute and in the application and scientific-educational process of specialists in hygiene and health ecology, as well as other specialists who have to spend their specialist internship in the Institute, i.e., in the Department for Health Ecology, students of general medicine, dentistry, students at the three-year professional studies, postgraduates in the field of public health and doctoral studies in general medicine and public health, as well as in the continuing medical education of doctors - specialists in hygiene and health ecology;
- ★ Identifies priority problems and potential health risk situations in the Republic and submits related reports to the Ministry of Health;

- ★ Participates in the activities within the framework of the two-year cooperation agreement between the Ministry of Health and the World Health Organization in the field of health ecology;
- ★ The Head of the Department is a Full Professor, specialist in hygiene.

Two full professors, one associate professor, one assistant professor and one assistant are employed in the Department and they are also members of the Department of Hygiene at the Faculty of Medicine in Skopje. They are involved in the teaching and scientific research activities for the needs of the Institute and the Faculty of Medicine.

Divisions in the Department:

- ★ Division for Water Safety, Environmental Sanitation and Eco-toxicology
- ★ Division for Food Safety
- ★ Division for Nutrition and Health - Hygienic Check-up
- ★ Division for Occupational Medicine and Health Risks Assessment.

Division for Water Safety, Environmental Sanitation and Eco-toxicology

PHI Institute of Public Health of RNM continuously monitors the sanitary-hygienic situation in the supply of safe drinking water, the safety of natural mineral waters, the hygienic quality of surface waters used for bathing and recreation and wastewater, the quality of ambient air and the impact on people's health, as well as the level of environmental sanitation throughout the entire territory of the Republic of North Macedonia. The activities of IPH of RNM are included in the Program for Public Health in the Republic of North Macedonia (sanitary-hygienic part). The laboratory segment of these activities is completely realized in the laboratories of the Department of Chemical and Radiological Testing and partially in the Department of Microbiology at IPH of RNM.

Our laboratories are accredited for food and drinking water safety testing according to ISO 17025 (accreditation certificate No. LT – 005 from 2006 and re-accreditation from 2022).

As part of its activity, the Division for Water Safety, Environmental Sanitation and Eco-toxicology at the Department for Health Ecology professionally and methodologically coordinates and supervises the work of the sanitary and hygiene services in the Public Health Centers of the Republic of North Macedonia in the field of communal hygiene and health ecology.

The Division for Water Safety and Environmental Sanitation and Health Ecotoxicology actively cooperates with the Ministry of Environment and Spatial Planning in the process of approximation of the legislation of the Republic of North Macedonia with the EU legislation.

The professional substrate of the Division's activity is drawn from several segments of the Institute's overall activity:

- ★ study of the impact of environmental risk factors on human health;
- ★ monitoring and expert assessment of the sanitary-hygienic condition of public water supply facilities and the safety of drinking water;
- ★ monitoring and expert assessment of the pollution of surface waters for bathing and recreational purposes;

- ★ preparation of expert reports on the safety of natural mineral water for drinking and natural mineral water filling stations;
- ★ monitoring and expert assessment of the ambient air pollution and the impact on health of the exposed population with measures for prevention and improvement of human health;
- ★ preparation of expert reports on environmental protection for facilities that with their location and technology are potential environmental polluters;
- ★ providing expert opinions for A and B – integrated environmental permits;
- ★ revision of reports on environmental protection regarding assessment of the health-ecological character of the location and technology, with a concluding opinion and proposed measures of local and general nature;
- ★ field inspections, if necessary, taking appropriate samples and providing an expert opinion on the sanitary-hygienic condition of facilities and communal infrastructure activities;
- ★ preparation of reports on sanitary-protection zones around the springs used for public water supply with drinking water and natural mineral water filling stations;
- ★ regular inspection of the way of functioning and maintenance, in order to improve the condition of the filter stations for the conditioning of surface waters that are intended for drinking;
- ★ preparation and participation in creation of legal and by-laws in the health ecology segment;
- ★ teaching-scientific and research activity conducted by an expert team including Full Professor, Assistant Professor, Doctor specializing in hygiene and health ecology, Doctor of General Medicine, Graduate Nurse and Nurse.

Division for Food Safety

The following activities are carried out in the Division:

- ★ Evaluation of the safety of food products before they are placed at the market. The evaluation is made on the basis of analyses performed in the laboratories of the Institute with accredited methods.
- ★ Determining the nutritional value of food products based on laboratory analyses and by using tables for nutritional composition.
- ★ Health risk assessment of microbiological, chemical or physical contaminants in food.
- ★ Assessment of the chemical contamination of food from domestic production and trade, in terms of residues of mycotoxins and heavy metals.
- ★ Assessment of the average daily and weekly dietary intake of mycotoxins and heavy metals by the population.
- ★ Participation in drafting national programs and strategies, laws and by-laws, professional methodological guidelines related to food safety.
- ★ Trainings on basic knowledge of food safety and environmental protection intended for food operators, in accordance with positive legal regulations. For this purpose, a Manual on Basic Knowledge of Food Safety and Environmental Protection has been prepared and printed.

Division for Nutrition and Health - Hygienic Check-up

- ★ The Division for Nutrition and Health - Hygienic Check-up monitors and studies the diet of the population in RNM, especially of the vulnerable population groups, using modern dietary assessment methods and proposes appropriate intervention measures according to new scientific knowledge in the field of nutrition and public health.
- ★ Monitors and assesses health risk factors related to diet and lifestyle.
- ★ Assesses the nutritional status of population groups of interest with anthropometric, laboratory and functional tests, and in cooperation with the teams from the Centers for Public Health in RNM monitors the growth and development of children and students in the country.
- ★ Establishes methodological guidelines for the research in the field of nutrition and public health, for participation in training activities for specialists in the preventive branches of medicine, and also participates in scientific research and educational activities, as well as in implementation of domestic and international project activities.
- ★ Prepares promotional material in the field of nutrition and public health for the population or population groups of interest.
- ★ An expert team of doctors and other healthcare staff works in the division, and they give advice to people on reducing health risks related to nutrition.
- ★ Health and hygiene examinations are carried out in the Division in order to prevent infectious diseases of the employees in activities prescribed by the Rulebook on the method of performance, scope of examinations, types of examinations and deadlines for mandatory health and hygiene examinations of employees (Official Gazette of RM no. 152/2007 and no. 8/2008) and health safety of the people who use these services. The health and hygiene examinations are performed under the conditions, terms and manner prescribed in the above-mentioned Rulebook, based on the criteria prescribed in the Law on Protection of the Population from Infectious Diseases (Official Gazette of the RM No. 66/2004).

Division for Occupational Medicine and Health Risks Assessment

The Division for Occupational Medicine and Risk Assessment, Institute of Public Health of the Republic of North Macedonia, is the first authorized public health institution that performs the tasks derived from Article 20 of the Law on Safety and Health at Work (Official Gazette of the Republic of Macedonia 53/2013).

The supply of the Institute of Public Health with modern and sophisticated equipment, as well as the engagement of experts from various fields, including 12 doctors of science and 8 professors at different faculties in the country and abroad, enable interdisciplinary implementation of integrated preventive health care of workers. It enables identification of physical, chemical and biological hazards in the work environment, as well as their concentrations in the biological material of the professionally exposed workers. Thus, the Division for Occupational Medicine can completely realize all the elements of preventive medical examinations which are determined by the Decree on the type, method and scope of health examinations of employees (Official Gazette of the RM No. 60/2013).

The occupational medicine team that is led by an occupational medicine specialist and includes another occupational medicine specialist and a doctor specializing in occupational medicine, a biochemist with a degree in genetics and three graduate nurses with internal training for biological monitoring, in cooperation with experts from other laboratories (biochemical, microbiological, toxicological and radiological), enable monitoring of the health status of workers professionally exposed to:

- ★ ionizing and non-ionizing radiation and personal dosimetry monitoring,
- ★ biological hazards in the work environment and determination of infection markers in biological material (blood, urine, serum, etc.),
- ★ chemical hazards in the working environment and determination of biological markers of exposure in biological material (heavy metals, organic compounds – cyclic and acyclic hydrocarbons and their halogenated amino and nitro derivatives).

The Government of the Republic of North Macedonia appointed the Division for Occupational Medicine, Institute of Public Health, to function as a service laboratory for the needs of other authorized institutions for safety and health at work where they can deliver their samples for all analyses that require sophisticated and expensive equipment that they do not have (ICP-MS inductively coupled plasma mass spectrometry, atomic absorption spectrophotometry: with flame, graphite cuvette and with hydride generation, liquid chromatography, gas chromatography, infrared chromatography, thermoluminescent dosimetry for ionizing radiation, complete bacteriological, virological and parasitological diagnosis for all occupational infectious diseases and determination of exposure markers).

The Division for Occupational Medicine, Institute of Public Health, is authorized by the Government of the Republic of North Macedonia to be a Training Center for Occupational Health responsible for organization of training for licensing professionals that work in this field.

The Division for Occupational Medicine, also works on the analysis of work-related injuries in the Republic of North Macedonia, collects and processes data on work performed by authorized occupational health institutions, maintains the register for occupational diseases and work-related injuries and other activities necessary for monitoring the conditions in this area. It cooperates with the State Statistics Office for integrated data collection and management of the above-mentioned registers.



D) Microbiological activity

5. DEPARTMENT FOR MICROBIOLOGY

Head: Dugagin Osmani, MD, spec. microbiol.

Activities of the Department for Microbiology:

- ★ performs microbiological examinations of the causes of infectious diseases, their identification and gives a specialist-consultative opinion;
- ★ monitors antimicrobial susceptibility and the most common antimicrobial resistance to invasive bacterial strains throughout the country utilizing the CAESAR network;
- ★ microbiological monitoring of infectious diseases of public health significance in R. N. Macedonia in accordance with the Law on the Protection of the Population from Infectious Diseases and other legal regulations;
- ★ participates in microbiological investigation of epidemics/pandemics from microbial agents by identifying the sources of infection, germ carriers and routes of transmission; performs molecular diagnostics of infectious agents (molecular microbiology), detection of genes for microorganism resistance with resistance to one or more groups of antibiotics; performs seroprevalence studies in the population for specific infectious diseases;
- ★ serves as a national laboratory for diagnosis and monitoring of influenza, HIV, measles, rubella, arbovirus infections (West Nile virus, Zika and others), hemorrhagic fever viruses (Hantaan virus and others) and other diseases of public health significance, and in accordance with the International Health Regulations (2005) and regulations of R.N. Macedonia;
- ★ provides expert-methodological assistance to the Ministry of Health in the field of microbiology;
- ★ performs typing of the causative agents;
- ★ medical entomological examinations and vector mapping for endemic vector-borne diseases in R.N. Macedonia
- ★ laboratory control of the undertaken measures (sterilization, immunization);
- ★ performs mandatory microbiological diagnosis, health and other examinations anticipated

by the Law on the Protection of the Population from Infectious Diseases and other legal regulations;

- ★ microbiological examinations of water, food products, food, premises and equipment for production, processing and distribution of food products with evaluation of the microbiological correctness according to food regulations;
- ★ performs microbiological control in healthcare organizations (operating rooms, resuscitation rooms, and other premises, instruments, materials, etc.);
- ★ coordinates the work and provides expert-methodological assistance to the Centers for Public Health in R. N. Macedonia in the field of microbiology;
- ★ creates and implements professional-medical doctrinal criteria in the field of microbiology;
- ★ in collaboration with educational institutions in R. N. Macedonia participates in the educational process and gives professional support in enriching the knowledge of healthcare workers and collaborators in the field of microbiology;
- ★ participates in the realization of scientific research projects in the field of microbiology;
- ★ participates in the educational process and enables professional development of healthcare workers and collaborators in the field of microbiology;
- ★ performs laboratory tests of drinking water, surface and waste water, monitors the pollution of interstate waters and watercourses, performs current sanitary supervision over drinking water;
- ★ performs bacterial endotoxin test (LAL test) according to the European Pharmacopoeia (Ph. Eur 2.6.14) for testing parenteral drugs, irrigation preparations, hemodialysis water, hemodialysis solutions;
- ★ expert assessment of quality control documentation and assessment of packaging of an imported batch of a biological drug/vaccine;
- ★ performs testing of sterility and microbiological purity of raw materials for drugs and finished drugs, herbal medicinal products and extracts;
- ★ performs testing of raw materials for drugs and finished drugs in terms of microbiological purity and sterility in accordance with the requirements of the European pharmacopoeia,
- ★ performs testing of cosmetic preparations in terms of microbiological quality,
- ★ performs testing of antimicrobial efficacy of disinfectants,
- ★ collaborates with international reference laboratories in the field of microbiology, and participates in international networks for monitoring and diagnostics of microbiological agents of public health significance.
- ★ Has successful collaboration with international health authorities such as WHO, ECDC and others.
- ★ The Department of Microbiology will continuously strive to monitor and introduce new microbiological methods according to the latest achievements in the field of microbiology, based on evidence-based medicine.

The Department consists of the following divisions:

1. Division for Virology
2. Division for Bacteriology
3. Division for Microbial Testing of Food and Medicines
4. Division for Parasitology

Division for Virology

The Division for Virology and Molecular Diagnostics is the only one of this kind in the Republic of North Macedonia. It was founded in 1960 with the aim of monitoring, study and laboratory diagnosis of viral diseases.

The most modern serological (immunoenzyme and immunoblot) and molecular diagnostic methods are applied, as well as isolation of viruses in cell cultures, in line with the world literature and WHO recommendations.

Since 2005 the Division has been given the status of the National Laboratory for Measles and Rubella in R. North Macedonia by the WHO.

Since 2006 the HIV Laboratory has been designated as the Reference Laboratory for HIV/AIDS in R. North Macedonia, which also includes a counseling center for free testing and counseling.

The Influenza Laboratory has been nominated by the Ministry of Health as a National Influenza Center and is included in the WHO Program for External Quality Assessment for Influenza Virus Detection.

On 17th of January, 2020, the diagnosis of the pandemic SARS-CoV-2 (Novel corona virus 2019-nCoV) was introduced for the first time in the country.

The Division is the only one in the country which was given responsibility by the WHO to maintain the status of a poliomyelitis-free country.

The following analyses are being performed in the Laboratory:

Detection of RNA/DNA with RT PCR of the following viruses:

- | | |
|---------------------------------------|---------------------------------------|
| - <i>Human Adenovirus A/B</i> | - <i>Respiratory Syncytial virus</i> |
| - <i>Coronavirus 229E</i> | - <i>Morbili virus</i> |
| - <i>Coronavirus HKU1</i> | - <i>Rubella virus</i> |
| - <i>Coronavirus NL63</i> | - <i>West Nile virus</i> |
| - <i>Coronavirus OC43</i> | - <i>Denga virus</i> |
| - <i>MERC- CoV</i> | - <i>CHIKU virus</i> |
| - <i>SARS -CoV-2</i> | - <i>Zika virus</i> |
| - <i>Human Metapneumovirus</i> | - <i>CMV</i> |
| - <i>Human Rhinovirus/Enterovirus</i> | - <i>Epstein Bar virus</i> |
| - <i>Influenza A</i> | - <i>Human Herpes virus 6</i> |
| - <i>Influenza B</i> | - <i>Varicella Zoster virus</i> |
| - <i>Parainfluenza virus1</i> | - <i>Human Herpes virus 1</i> |
| - <i>Parainfluenza virus2</i> | - <i>Human Herpes virus 2</i> |
| - <i>Parainfluenza virus3</i> | - <i>Human monkeypox virus (MPXV)</i> |
| - <i>Parainfluenza virus4</i> | |

★ subtyping of Influenza A and B viruses,

★ detection and characterization of VOC and VOI variants of SARS-CoV-2 virus.

Since January 2021, sequencing of the entire genome of SARS-CoV-2 virus has been underway, as well as of the rest of the respiratory viral panel.

Since July 2022, detection of MPXV as well as sequencing of the genome of Monkeypox virus is being done.

Detection of antigen or antibodies to viruses is done with:

- ★ ELISA – Enzyme-linked Immunosorbent Assay
- ★ ELFA – Enzyme-linked Fluorescence Assay
- ★ IEHT – Immunoenzymatic Chemiluminescent Test
- ★ IHT – Immunochromatographic Test
- ★ WB - Western blot Test.

- Cytomegalovirus (CMV) IgM	blood
- Cytomegalovirus (CMV) IgG	blood
- Cytomegalovirus (CMV) IgG Avidity- determining the age of antibodies	blood
- HAV IgM antibodies	blood
- HAV total antibodies	blood
- HBs antigen	blood
- HBs total antibodies	blood
- HBc total antibodies	blood
- HBc IgM antibodies	blood
- HBe antigen	blood
- HBe total antibodies	blood
- HCV antibodies	blood
- HCV RNA – quantitative	blood
- HIV 1/2 antibodies	blood
- HIV integral (Ag +At)	blood
- HIV duo (P24 Ag +At)	blood
- Herpes simplex virus (HSV2) IgM antibodies	blood
- Herpes simplex virus (HSV2) IgG antibodies	blood
- Herpes simplex virus (HSV1) IgM antibodies	blood
- Herpes simplex virus (HSV1) IgG antibodies	blood
- Herpes zoster virus – Varicela (VZV) IgM antibodies	blood
- Herpes zoster virus – Varicela (VZV) IgG antibodies	blood
- Morbilli IgM antibodies	blood
- Morbilli IgG antibodies	blood
- Mumps (parotitis) IgM antibodies	blood
- Mumps (parotitis) IgG antibodies	blood
- Rubella IgM antibodies	blood
- Rubella IgG antibodies	blood
- West -Nile virus IgM antibodies	blood
- West -Nile virus IgG antibodies	blood
- Hantaan virus IgM antibodies	blood
- Hantaan virus IgG antibodies	blood

- TBE virus IgM antibodies	blood
- TBE virus IgG antibodies	blood
- Congo Crimean Hemorrhagic Fever virus IgM antibodies	blood
- Congo Crimean Hemorrhagic Fever virus IgG antibodies	blood
- Parvovirus B19 IgM antibodies	blood
- Parvovirus B19 IgG antibodies	blood
- Enteroviruses (Rota, Noro, Astro, Adeno)	feces

Immunoenzymatic tests are also performed in this Division for detection of antibodies against the following microorganisms:

- <i>Borrelia burgdorferi</i> (Lyme borreliosis) IgM antibodies	blood
- <i>Borrelia burgdorferi</i> (Lyme borreliosis) IgG antibodies	blood
- <i>Toxoplasma gondii</i> IgM antibodies	blood
- <i>Toxoplasma gondii</i> IgG antibodies	blood
- <i>Toxoplasma gondii</i> IgG Avidity– determining the age of antibodies	blood
- Q fever phase ½ IgM antibodies	blood
- Q fever phase ½ IgG antibodies	blood
- <i>Helicobacter pylori</i> IgG antibodies	blood

Division for Bacteriology

Bacteriological diagnostics of materials is being carried out according to clinical and epidemiological indications in the Division for Bacteriology. Microbiological control of non-living environment is performed: microbiological monitoring of air quality, microbiological correctness of dry and wet sterilization/dry heat and moist heat sterilization/ with biological indicators and microbiological correctness of non-living environment - objects and surfaces.

Particular attention is paid to registering and monitoring bacterial strains resistance to antimicrobial agents.

Also, in the laboratory, bacteriological analyses are made aimed at discovering the presence of bacteria in persons who are subject to sanitary examinations in accordance with the Law on Health Care of the Republic of North Macedonia.

Bacteriological services:

- ★ Bacteriological examination of nasal swab
- ★ Bacteriological examination of throat swab
- ★ Bacteriological examination of oral cavity (gingiva, aphthae, tongue) swab
- ★ Bacteriological examination of sputum
- ★ Bacteriological examination of bronchoalveolar lavage – aerobic
- ★ Bacteriological examination of skin changes
- ★ Bacteriological examination of eye swab (conjunctiva)
- ★ Bacteriological examination of external ear swab
- ★ Bacteriological examination of middle ear swab – aerobic
- ★ Bacteriological examination of middle ear swab – anaerobic
- ★ Bacteriological examination of umbilical swab

- ★ Bacteriological examination of a swab from wound, burn, fistula – aerobic
- ★ Bacteriological examination of a swab from wound, burn, fistula – anaerobic
- ★ Bacteriological examination of a swab from branula, cannula, tube, catheter, drain – aerobic
- ★ Bacteriological examination of a swab from branula, cannula, tube, catheter, drain – anaerobic
- ★ Bacteriological examination of punctate, abscess, exudate – aerobic
- ★ Bacteriological examination of punctate, abscess, exudate – anaerobic
- ★ Bacteriological examination of dialysate – aerobic
- ★ Bacteriological examination of dialysate – anaerobic
- ★ Blood culture – aerobic
- ★ Blood culture – anaerobic
- ★ Bacteriological examination of urine
- ★ Bacteriological examination of urethral swab
- ★ Bacteriological examination of urethral swab for mycoplasmas (*Mycoplasma hominis* and *Ureaplasma urealyticum*)
- ★ Bacteriological examination of vulva smear
- ★ Bacteriological examination of vaginal and cervical swabs
- ★ Bacteriological examination of vaginal and cervical swabs for the presence of mycoplasmas (*Mycoplasma hominis* and *Ureaplasma urealyticum*)
- ★ Bacteriological examination of sperm (spermoculture) – aerobic
- ★ Bacteriological examination of sperm (spermoculture) – anaerobic
- ★ Bacteriological examination of feces (coproculture)
- ★ Bacteriological examination of rectal smear
- ★ Serotyping of bacteria from the genus *Salmonella* and *Shigella*
- ★ TPHA – *Treponema pallidum* – specific anti-treponema antibodies
- ★ RPR – *Treponema pallidum* – non-specific anti-treponema antibodies
- ★ *Francisella tularensis* – agglutination slide test
- ★ *Francisella tularensis* – Real-time polymerase chain reaction for detection of nucleic acids
- ★ Real-time polymerase chain reaction for detection of *Bordetella pertussis*
- ★ Real-time polymerase chain reaction for detection of *Legionella pneumophila*
- ★ Real-time polymerase chain reaction for detection of *Treponema pallidum*
- ★ Real-time polymerase chain reaction for detection of *Neisseria gonorrhoeae*
- ★ Examination of susceptibility of isolated microorganisms to antibiotics and chemotherapeutics (antibiogram)
- ★ Multiplex PVR for detection of genes resistance to certain antimicrobial agents.

Division for Microbial Testing of Food and Medicines

- *Laboratory for microbiological control of food and water*

The Laboratory has implemented the quality system MKC EN ISO 17025:2018 as part of the program and routine activities, and it provides realization of the following analyses:

- ★ Microbiological control of air, swabs from work surfaces and hands of food industry employees;
- ★ Microbiological control of items for general use

- ★ Drug testing laboratory – sterility of the finished drugs and medical devices that are declared sterile (Ph. Eur. 2.6.1);
- ★ Microbiological purity of raw materials for drugs, finished pharmaceutical/dosage forms, primary packaging (Ph.Eur 5.1.4);
- ★ Microbiological purity of herbal medicinal products and extracts (Ph.Eur 5.1.8);
- ★ Microbiological purity of cosmetic products (Official Gazette 94/2010).

Since May 2008 the Laboratory has been ISO 17025 accredited and works in accordance with the legal regulation for testing microbiological food quality “Regulations for special requirements for **food** safety in relation to microbiological criteria” (Official Gazette of the Republic of Macedonia 100/2013; 229/2020).

The work of the Laboratory includes:

1. Determination and identification of *Salmonella* (ISO 6579: 2017);
2. Determination of coagulase positive *Staphylococcae* (ISO 6888-1: 2008);
3. Enumeration of sulfite-reducing *Clostridia* (ISO 15213:2003);
4. Enumeration of *Clostridium perfringer* (ISO 7937: 2004);
5. Enumeration of beta glucuronidase positive *E. coli* (ISO 1664 –2: 2017);
6. Confirmation of *E. coli* 0157:H7 (ISO 16654: 2001);
7. Confirmation of *Listeria monocytogenes* (ISO 11290-2: 2018);
8. Confirmation of *Campilobacter spp* (ISO 10272 - 1: 2017);
9. Confirmation of *Yersinia enterocolitica* (ISO 10273 - 2017);
10. Confirmation of *Bacillus cereus* (ISO 7932: 2020);
11. Confirmation of *Enterobacteriaceae* (ISO 21528-2: 2017);
12. Confirmation of *Cronobacter sakazakii* (ISO/TS 22964: 2017);
13. Confirmation of *Vibrio parahemolyticus* (ISO 8914: 2007);
14. Confirmation of *Lactobacilli*;
15. Confirmation of *Streptococcus species*;
16. Enumeration of the total number of aerobic mesophilic bacteria (ISO 4833: 2013);
17. Enumeration of yeasts and molds (ISO 21527-1,2: 2008);
18. Confirmation of VIDAS *Salmonella* (SPT) ELFA method (AFNOR certificate);
19. Confirmation of VIDAS *L. monocytogenes Xpres* (LMX) ELFA method (AFNOR certificate)
20. Confirmation of VIDAS *E. coli* 157:H7 (ECPT) ELFA method (AFNOR certificate)
21. Confirmation of VIDAS *Campylobacter* (CAM) ELFA method (AFNOR certificate)
22. Confirmation of VIDAS *Staph enterotoxin* (SET2) ELFA method (AOAC certificate).

The examination of the microbiological safety of **water** is done in accordance with the “Regulations for the safety of water, mineral, spring, and other waters” (Official Gazette of RM 46/2008; 129/2014 and 183,184/2018).

The work of the Laboratory includes:

23. Determination of MNP of coliform organisms and expected TT *E. coli* (ISO 9308-2:2016);
24. *E. coli* and coliform bacteria with MF (ISO 9308 -1: 2017);

25. Total number of aerobic bacteria at 22°C in 1 ml (ISO 6222: 1999);
26. Total number of aerobic bacteria at 37°C in 1 ml (ISO 6222: 1999);
27. Determination of the presence of *Enterococcus* in water with MF (ISO 7899 – 2: 2000);
28. Determination of the presence of *Legionella pneumophila* with MF (ISO 11731 – 1.2: 2018);
29. Determination of the presence of *Pseudomonas aeruginosa* with MF (ISO 16266: 2006);
30. Determination of the number of *Clostridium perfringes* with MF (ISO 14189: 2017);
31. Detection and enumeration of sulfite-reducing *Clostridii* (ISO 26461 – 2: 2017);
32. Determination of the presence of *Proteus species*, *Salmonella*, *Shigella* and others.

- *Laboratory for microbiological control of drugs, sterility and cosmetic preparations*

- ✧ Testing the sterility of drugs using membrane filtration and direct seeding methods, including preparations for parenteral application and other medical products that are declared sterile, such as eye drops, medical devices, etc.;
- ✧ Testing for bacteriological purity of all dosage forms that are used orally, topically or rectally, including tablets, capsules, suppositories, creams, ointments, vagitoriers, as well as other preparations that may be of synthetic or organic origin (plant, mineral or animal) by the method of direct planting on a suitably prepared sample or by the membrane filtration method;
- ✧ Examination of bacteriological purity of water for pharmaceutical purposes by membrane filtration method;
- ✧ Examination of bacteriological purity of primary packaging such as capsules, Al-foils, PVC-foils, glass bottles, plastic vials, droppers, alveoli for suppositories and other packaging with methods of washing or the method of taking a swab and directly planting the prepared sample;
- ✧ Examination of bacteriological purity of medical cosmetics and cosmetic preparations that find daily usage among the general population, such as products for maintaining personal hygiene and products for face and body beautification.

Modernization and providing additional necessary laboratory equipment are also a priority for this Laboratory, as well as initiation of the accreditation process of the Laboratory for control of drugs and cosmetic products and preparations for implementation of ISO 17025 and ISO 15189 standards.

- *Bacterial endotoxin testing laboratory*

This Laboratory has implemented the quality system MKCENISO 17025:2018.

The following analyses are being performed according to valid standards and methods (Ph.Eur/ USP/BP):

- ✧ Examination of the presence/absence of bacterial endotoxin in parenteral preparations for human use, substances for pharmaceutical use, preparations for irrigation with the gel clot method;
- ✧ Examination of the presence/absence of bacterial endotoxin in medical preparations

(parenteral drugs for human use, serums, vaccines, substances for pharmaceutical purposes, irrigation preparations, hemodialysis water, hemodialysis solutions) according to the specifications and methods described in the valid editions of the European Pharmacopoeia (Ph.Eur.), American Pharmacopoeia (USP), British Pharmacopoeia (BP) as well as specifications and valid methods of the manufacturer of the finished preparation (Ph. Eur. 2.6.14, LAL test - gel clot method, accredited method according to MKC EN ISO / IEC 17025:2018).

- ★ The Bacterial endotoxin testing laboratory plans to introduce a bacterial endotoxin test in medical devices using the gel clot technique.
- ★ The Laboratory provides testing of bacterial endotoxin supplied by the Agency for Medicines and Medical Devices of R. N. Macedonia, public health institutions which have signed an agreement with the Institute, as well as by private legal entities.

Division for Parasitology

The Division for Parasitology performs parasitological diagnostics of medically significant protozoa and helminths and their developmental forms. The routine and program activities include:

- ★ determination and identification of parasites in human samples
- ★ determination and identification of parasites in water.

The Division for Parasitology performs parasitological examinations which, according to legal regulations, are subject to health supervision:

- ★ of persons coming from countries where there is an epidemiological risk of certain infectious diseases,
- ★ of persons employed in the production and trade of animal products and drinking water in order to prevent spread of parasitic diseases - sanitary examinations.

The Division for Parasitology monitors the quality of drinking water, surface and waste water in accordance with legal regulations. According to the requirements for accreditation (ISO 17025), the Division has introduced a fully automated system for membrane filtration specially designed and intended for parasitological testing of water.

Analyses conducted in the Division for Parasitology are as follows:

- ★ Feces for cysts and vegetative forms of protozoa and eggs of helminths – native preparation
- ★ Feces for cysts and vegetative forms of protozoa and helminth eggs - concentration method
- ★ Cellophane (perianal) swab for *Enterobius vermicularis*
- ★ Detection of *Trichomonas vaginalis* from genital tract, urethral swabs, urine, ejaculate (real-time polymerase chain reaction, native preparation, culture)
- ★ Biopsy material and punctate from organs for tissue parasites (native, differential staining)
- ★ Detection of parasites in body fluids and secretions (native, differential staining)
- ★ Blood smear for microfilariae (Knott's method)
- ★ Detection of *Giardia lamblia* antigen (immunochromatographic)
- ★ Detection of *Cryptosporidium* spp. antigen (immunochromatographic)

- ★ Detection of *Plasmodium falciparum* antigen (immunochromatographic)
- ★ Detection of *Plasmodium vivax*, *Plasmodium ovale*, *Plasmodium malariae* antigen(immuochromatographic)
- ★ Detection of IgM/IgG antibodies to microfilariae (immunochromatographic)
- ★ Detection of IgM antibodies against *Leishmania donovani* (indirect immunofluorescence)
- ★ Detection of IgG antibodies against *Leishmania donovani* (indirect immunofluorescence)
- ★ Detection of IgM/IgG antibodies against *Leishmania donovani* (immunochromatographic)
- ★ Detection of IgG antibodies against *Echinococcus granulosus* (indirect immunofluorescence)
- ★ Detection of IgA antibodies against *Echinococcus granulosus* (indirect immunofluorescence)
- ★ Detection and differentiation of *Echinococcus granulosus* / *Echinococcus multilocularis* (Western blot)
- ★ Detection of antibodies *Brucella spp.* (qualitative BAB test, quantitative - indirect hemagglutination)
- ★ Detection of *Entamoeba histolytica* antibodies (quantitative - indirect hemagglutination)
- ★ Detection of *Chlamydia trachomatis* from genital tract - urethral swabs, from urine, from conjunctiva (real-time polymerase chain reaction)
- ★ Detection of *Plasmodium species* in blood (real-time polymerase chain reaction)
- ★ Macroscopic and microscopic determination of helminths
- ★ Macroscopic and microscopic determination of arthropods.



6. DEPARTMENT FOR TESTING AND CONTROL OF DRUGS AND MEDICINES

Head: Katerina Starkoska, grad. pharm. spec.

Activities of the Department for Testing and Control of Drugs and Medicines:

The Department for Testing and Control of Drugs and Medicines with the authorization of the Agency for Medicines/Drugs and Medical Devices of R. North Macedonia, based on the Law on Medicines and Medical Devices/Agents (Official Gazette of the Republic of Macedonia no. 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16, 83/18, 113/18, 245/18 and Official Gazette of RNM" No. 28/21) as well as by-laws, conducts independent testing, that is, analytical testing and quality control of drugs in order to confirm their compliance with previously approved quality specifications.

Analytical testing is done in line with the guidelines of the valid editions of the European Pharmacopoeia, British Pharmacopoeia and American Pharmacopoeia, the principles and guidelines of Good Laboratory Practice and WHO recommendations.

The Department for Testing and Control of Drugs and Medicines explicitly defines the mission, vision and goals for establishing a robust system for quality control of drugs/medicines. Within the frameworks of joint actions with the Macedonian Agency for Medicines/Drugs and Medical Devices, this Department also defines and coordinates the national priorities in the health system.

The activities conducted by this Department are at the request of the Macedonian Agency for Medicines/Drugs and Medical Devices and the State Sanitary and Health Inspectorate at the Ministry of Health.

The Department for Testing and Control of Drugs and Medicines has the responsibility to confirm that cosmetic products and hygiene cleaning products in the household and industry are safe and do not harm human health by applying the Law on Safety of Cosmetic Products (Official Gazette no. 55/07) and the by-laws: Rulebook on data about the composition of detergents that should be indicated on the packaging, as well as the general and special regulations for labeling the detergent packaging - Official Gazette no. 84/2011, Rulebook on data about the composition of detergents - Official Gazette no. 84/2011 and Regulation/Directive banning production, trade and use of detergents for machine washing of textile products with phosphorus content in organic or inorganic form of more than 0.5%, as well as European Regulation.

The goal/task of the Department is to provide the market with medicines, herbal preparations, preparations of biological origin, cosmetic products, hygiene cleaning products and other products with solid and reliable quality.

The activities are realized according to the quality system, i.e., the standard MKS ISO/IEC 17025:2018 (accredited techniques in the Division for Physico- Chemical Testing, Division for Pharmaco-Technological Testing, Division for Cosmetology and Bacterial endotoxin testing laboratory, which is done in the Department of microbiological control of food and drug quality).

The Department for Testing and Control of Drugs and Medicines is organized into three divisions:

- ★ Division for Physico- Chemical Testing
- ★ Division for Pharmaco-Technological Testing
- ★ Division for Cosmetology

Two divisions in the Department for Microbiology realized activities for the Department for Testing and Control of Drugs and Medicines (microbiological hygiene, sterility and bacterial endotoxin testing).

Division for Physico- Chemical Testing

Division for Pharmaco-Technological Testing

The following physico-chemical quality control of medicines/drugs is being performed in the Divisions:

- ★ regular quality control of every medicine placed on the market in the Republic of North Macedonia, at least once every five years;
- ★ quality control of the first batch of the drug after obtaining an approval for placing it on the market;
- ★ quality control at the request of the Macedonian Agency for Drugs/Medicine for obtaining an approval for placing the medicine on the market or after issuing an approval at the request of the inspection authority;
- ★ specific quality control of specific categories of drugs at the request of the Macedonian Agency for Drugs/Medicine;
- ★ identification and determination of active components cannabidiol (CBD), (-)-D9- trans-tetrahydrocannabinol (D9-THC) and degradation product cannabinol in medicinal cannabis extracts and finished products that contain medicinal cannabis extract.

The following techniques are used for conducting laboratory control: high-performance liquid chromatography (HPLC), gas chromatography (GC), infrared (IR), ultraviolet (UV) and visible (Vis) spectroscopy, gravimetric techniques, volumetric techniques, in line with the specifications and methods described in the current editions of the European Pharmacopoeia (Ph.Eur.), United States Pharmacopoeia (USP), British Pharmacopoeia (BP) and specifications and valid methods provided by the manufacturer of the finished product.

In addition to the above-mentioned activities, an expert evaluation of quality control documentation and packaging evaluation of an imported batch of biological drug/vaccine is also performed.

Division for Cosmetology

This Division is involved in activities of testing quality and safety of cosmetic products in accordance with the Law on the Safety of Cosmetic Products - Official Gazette no. 55/07, Regulation 1223/2009, List of products considered to be cosmetic products - Official Gazette No. 156/2007; List of substances used in the process of production of cosmetic products - Official Gazette No. 89/2010; List of preservatives which usage is allowed in cosmetic products - Official Gazette No. 89/2010; Rulebook on the content and method of cosmetic products labeling - Official Gazette No. 98/2010; Rulebook on the criteria for microbiological and chemical purity of cosmetic products and on the methods for checking those criteria - Official Gazette No. 94/2010 and Rulebook for releasing of items of general use on the market - Official Gazette 26/83.

The Division confirms the adequacy/reliability of the quality specification and intended purpose of products for household hygiene maintenance in accordance with the following legal regulations: Rulebook on placing items of general use on the market - Official Gazette 26/83; Rulebook on the content of detergents that should be indicated on the packaging, as well as general and special rules for labelling of detergent packaging - Official Gazette no. 84/2011; Rulebook on data about the composition of detergents - Official Gazette no. 84/2011; Regulation/Directive banning production, trade and use of detergents for machine washing of textile products with phosphorus content in organic or inorganic form of more than 0.5%. The Division performs analyses which goal is placing of products from the group of cosmetic products on the market (issuing a safety certification).

The following groups of products are subject to control:

- ★ Personal hygiene products/items
- ★ Products/items intended for hygiene and care of infants and small children
- ★ Products from the group of decorative cosmetics
- ★ Household cleaning products
- ★ Products for professional use
- ★ Raw materials for the production of cosmetic products and products for personal hygiene and household cleaning.

The Division uses sophisticated equipment for accomplishing its activities and analyses: 4 HPLC systems, GC, FTIR spectrophotometer, UV/VIS spectrophotometer, apparatus for the release of active substance from dosage pharmaceutical forms - solubility apparatus, disintegration apparatus, pH meter, AAS - apparatus for determination of heavy metals, apparatus for bacterial endotoxin testing (LAL test - gel clot method) and other equipment.

The staff employed is multidisciplinary and includes a doctor of pharmacy, pharmacists specialized in testing and quality control of drugs, a specialist in microbiology, a specialist in biology, a doctor of chemical sciences, a master of chemical sciences, pharmacy graduates, chemical engineering graduates, a biology graduate and chemical technicians.



7. DEPARTMENT FOR CHEMICAL AND RADIOLOGICAL TESTING

Head: Prof. Zorica Arsova Sarafinovska, PhD

Activities of the Department for Chemical and Radiological Testing

This Department is an organizational-technical unit that encompasses some of the laboratories in the PHI IPH of RNM. The laboratory activities and tasks of the IPH appointed/specified by the Law on Public Health of RNM are fully realized. The organization, work tasks, authorizations and responsibilities of the employees are regulated by the Statute and the Regulation for the internal organization and systematization of workplaces in PHI IPH of RNM.

The laboratory tests are performed in accordance with the valid national and international standards and regulations, with constant care for the needs and requirements of the users and a continuous increase in the reliability of the results.

The quality in the performance of laboratory analyses is ensured by preparation of harmonized professional standards and guidelines, continuous professional development of employees in the field of public health, implementation and maintenance of a laboratory system for management and accreditation of laboratories.

The Department consists of:

1. Division for Food Quality Testing
2. Division for Water Quality Testing
3. Division for Testing of Items for Common Use
4. Division for Contaminants and Eco-toxicology
5. Division for Metal Testing
6. Division for Radiation Protection

Division for Food Quality Testing

The Food Quality Testing Laboratory has been accredited according to ISO 17025 standard since 2006 for applying the following methods:

- ★ Determination of water in food products (0201 RU 7.2.65);
- ★ Determination of ash in food products (0201 RU 7.2.66);
- ★ Determination of acid level and acidity in animal and vegetable fats and oils (ISO 661:2003);
- ★ Determination of saponification number in animal and vegetable fats and oils (ISO 3657:2002);
- ★ Determination of unsaponifiable matter in animal and vegetable fats and oils (ISO 3596:2000);
- ★ Determination of titration acidity in fruit and vegetable products (ISO 750:1998);
- ★ Determination of salt content in butter (ISO 1738:2004);
- ★ Determination of fat content in milk (ISO 2446:1976, ISO 488:1983);
- ★ Determination of acidity of milk (Regulations on methods of physical and chemical analyses of milk and milk products - Official list of SFRY, no. 32/83);
- ★ Determination of milk dry matter (Regulations on methods of physical and chemical analyses of milk and milk products - Official list of SFRY, no. 32/83);
- ★ Determination of acidity of sour milk and yogurt (Regulations on methods for physical and chemical analyses of milk and milk products - Official list of SFRY, no. 32/83);
- ★ Determination of dry matter in sour milk and yogurt (Regulations on methods for physical and chemical analyses of milk and milk products - Official list of SFRY, no. 32/83);
- ★ Determination of water content in grain and grain products (ISO 712:2009);
- ★ Determination of ash in grain and grain products (ISO 2171:2007)
- ★ Determination of total ash in tea (ISO 1575:1987);
- ★ Determination of mass loss in tea (ISO 1573:1980);
- ★ Determination of total acids such as acetic one in vinegar (0201 RU 7.2.35);
- ★ Determination of moisture content in starch (ISO 1666:1996);
- ★ Determination of ash in starch (ISO 3593:1981);
- ★ Determination of ash insoluble in hydrochloric acid in fruit and vegetable products (ISO 763:2003);
- ★ Determination of salt iodization (UNICEF/ROSCA, 1989);
- ★ Determination of preservatives, sodium benzoate and potassium sorbate with HPLC in soft drinks (§35 LMBG L 00.00-9, 1984);
- ★ Determination of artificial sweeteners (saccharin, aspartame and acesulfame-K) in soft drinks (§35 LMBG L 00.00, 2001);
- ★ Determination of fatty acid composition in food by gas chromatography with GC-FID ISO 12966-2;
- ★ Determination of nitrate content in vegetables and vegetable products with HPLC method (ISO 12014:2-2018);

- ★ Determination of gluten (allergen) in food products by ELISA method (AOAC- OMA (2012.01);
- ★ Determination of water in meat and meat products (ISO 1442:2022);
- ★ Determination of ash in meat and meat products (ISO 936:2022);
- ★ Determination of salt in food;
- ★ Determination of pH in fruit and vegetable products (ISO 1842 : 1991);

The Food Quality Testing Laboratory is included in quality control of the following groups of food products:

- ★ non-alcoholic and alcoholic beverages
- ★ confectionery products
- ★ flour and mill products
- ★ fruit and vegetable products
- ★ milk and milk products
- ★ meat and meat products
- ★ fats and oils
- ★ raw materials and additives in the food industry
- ★ spices and herbs
- ★ aromas and concentrates for refreshing beverages
- ★ baby food
- ★ dietary supplements.

The testing of parameters of food quality products is done in compliance with standard and prescribed methods according to the valid national regulations and EU Directives.

The following parameters are analyzed in the test samples: water content, dry matter, ash, proteins, fats, sugars, dietary fibers, content of organic acids, alcohol, total extract, relative density, saponification number, iodine number, acid degree, etc.

Based on the examined chemical parameters, the energy value of the food products is also determined.

In addition, the presence of various additives such as: preservatives (benzoates, sorbates), sweeteners (acesulfame, aspartame, saccharin), artificial food dyes, Sudan dyes, is examined in the food products.

The presence of vitamins (hydro- and liposoluble) is determined in nutritional supplements, which are also analyzed for the presence of some active components such as: coenzyme Q10, hesperidin, diosmine, isoflavones, quercetin, ginsenosides, quinic acid, glucosamine, chondroitin, etc.

Division for Water Quality Testing

The Water Quality Testing Division performs examinations of different types of water including:

- ★ drinking water
- ★ natural mineral water

- ★ spring water
- ★ packaged waters (drinking waters and natural mineral waters)
- ★ technical and technical-technological waters
- ★ bathing waters
- ★ surface water.

The Division is accredited in compliance with ISO 17025:2018 standard for the following methods:

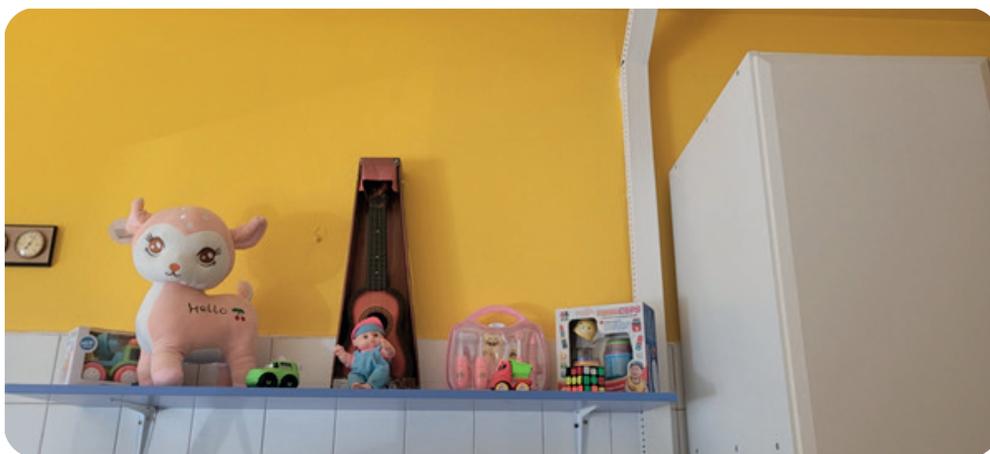
- ★ Photometric determination of color (ISO 7887:2013);
- ★ Determination of total dissolved dry residue at 105°C, 180°C and 260°C; (“Drinking water– Standard methods for testing hygiene” S. Škunca-Milovanović, R. Feliks, B. Đurović, Belgrade 1990);
- ★ Determination of pH (MKC ISO 10523:2013);
- ★ Determination of electrical conductivity (ISO 7888:1985);
- ★ Determination of permanganate index (KMnO₄ consumption) (ISO 8467:1993);
- ★ Determination of chlorides in water by Mohr method (ISO 9297:1989);
- ★ Determination of calcium content by EDTA titrimetric method (ISO 6058:1984);
- ★ Determination of magnesium content (ISO 6059:1984);
- ★ Determination of concentration of calcium and magnesium by EDTA titrimetric method (ISO 6059:1984);
- ★ Determination of alkalinity (total-m, compound-p and carbonate alkalinity) (ISO 9963) (m-alkalinity, p-alkalinity, carbonates, bicarbonates, hydroxides).

According to the Regulations for different types of water, the Division performs basic and periodic analysis, which includes the following tests:

- ★ Determination of anions by ion chromatography (fluorides, chlorides, nitrites, bromides, nitrates, phosphates and sulfates);
- ★ Determination of cations by ion chromatography (lithium, sodium, potassium, ammonium, magnesium and calcium);
- ★ Determination of heavy metals (iron, manganese, copper, zinc, lead, cadmium, cobalt, nickel and total chromium);
- ★ Determination of turbidity;
- ★ Determination of cations in water (MKC EN ISO 14911:2009);
- ★ Determination of anions in water (MKC EN ISO 10304-1:2013);
- ★ Determination of iron in water (MKC ISO 6332:2007);
- ★ Determination of manganese in water (MKC ISO 6333:2007).

Division for Testing of Items for Common Use

The Department for Testing of Items for Common Use is of huge importance, because it is the only Division accredited of this kind in RNM.



This Division performs examinations of the health safety of:

- ★ materials and products intended to come into contact with food products, which must meet general and special conditions, so that they do not affect the quality and safety of food and do not have harmful effects on consumers' health;
- ★ examinations of health correctness of materials and products intended to come into contact with skin and mucous membranes;
- ★ testing the health safety of children's toys.

The tests are conducted in accordance with the existing national legislation, which refers to items for general use and children's toys, as well as the latest EU Regulations and Directives.

Parameters tested on certain types of items are as follows:

- ★ complete migration of non-volatile substances,
- ★ specific migration of metals (Pb, Cd, Cr, Ni, Mn, Co, Zn, Fe, Cu),
- ★ specific migration of sum of primary aromatic amines,
- ★ release of color in test solution and
- ★ testing of mechanical and physical properties of children's toys.

The Division performs testing of the following items for general use (from import and domestic production):

- ★ dishes and utensils for cooking and storage of food products (made of glass, ceramics, wood, paper, metal, enamel)
- ★ packaging for groceries,
- ★ children's toys,
- ★ personal hygiene products,
- ★ household cleaning products,
- ★ utensils for small children and infants,
- ★ plastic granules,
- ★ machine parts and
- ★ packaging.

The Division is accredited according to ISO/IEC 17025 standard for the following methods:

- ✧ Determination of metals in ceramic objects in line with Directive 84/500/EEC and Official Gazette of the Republic of Macedonia No. 1/2013 (20130010005);
- ✧ Determination of the amount of primary aromatic amines in items made of plastic in line with “Amtliche Sammlung von Untersuchungsverfahren nach §35 LMBG (Lebensmittel- und Bedarfsgegenstände-gesetz)” L00.00-6 ;
- ✧ Determination of heavy metals in children’s toys from different materials in line with EN 71-3:2019.

Division for Contaminants and Eco-toxicology

The Division of Contaminants and Ecotoxicology performs testing of pesticide residues in the following food products: vegetables, fruits, grain and grain products, edible oils, drinking water, packaged water, surface water and others. Pesticides that are used to destroy various pests and improve the yield and protect plants must be tested in order to protect the health of the population and in agreement with the regulation on pesticides – Official Gazette no. 95/2021, where maximum tolerated permissible limits are defined if the pesticides are applied according to good production practice.

The Division also examines the presence of mycotoxins, which are secondary products of mold metabolism. According to the current regulation on contaminants (Official Gazette no. 227/2021), it is necessary to examine the presence of mycotoxins in grain and grain products, nut products, dried fruit, coffee and other products. The Division is included in testing the presence of mycotoxins in dry cannabis flowers in line with the European pharmacopoeia, and it is the first accredited laboratory for this type of analysis. All analyses are done as a routine, legal obligation, at the request of a client or inspection services from the Food and Veterinary Agency.

The Division is equipped with gas chromatography with mass detection (MS), FTD and ECD detectors and auxiliary equipment, which are used for determination of the following pesticide residues:

- ✧ phorate, terbufos, diazinon, chlorpyrifos-methyl, pirimiphos-methyl, malathion, fenthion, pendimethalin, buprofezin, ethion, benalaxyl, iprodione, bifenthrin, tebufenpyrad, azinphos-methyl, phosalone, azinphos-ethyl, boscalid, ethoprophos, methyl parathion, fenitrothion, malathion, parathion, fenamifos, phosmet, HCB (Hexachlorbenzene), trifluralin, alpha HCH, beta HCH, Lindane - gamma HCH, delta HCH, heptachlor, aldrin, dieldrin, endrin, 2,4'-DDE, 4,4'-DDE, 2,4'-DDD, 2,4'-DDT, 4,4'-DDD, 4,4'-DDT, alpha Endosulfan, beta Endosulfan, Endosulfan sulfate, alpha chlordane, imazalil, alpha Cypermethrin, acetamiprid, methoxychlor, deltamethrin in food products, water and cannabis flower.

Fluorimetry and ELISA method are used for determination of mycotoxins in the following products:

- ✧ Total aflatoxins (B1+B2+G1+G2) in nuts (peanuts, almonds, apricot kernels, pistachios, hazelnuts and cashews), cereals and corn, cannabis, nuts, dried fruit, spices, beer, oil;
- ✧ Ochratoxin A in cannabis, green coffee, cereal products, corn, spices, beer and wine;
- ✧ Deoxynivalenol in cereal products, corn and beer;
- ✧ Zearalenone in cereal products, corn and beer;
- ✧ Fumonisin in cereal products and corn.

The Division for Contaminants and Ecotoxicology is accredited in line with ISO 17025 standard from 2018 for the following methods:

- ✧ Determination of pesticide residues in fruits and vegetables by gas chromatography with mass detection (GC-MS);
- ✧ Determination of pesticides in water by gas chromatography with mass spectrometric detection (GC-MS);
- ✧ Fluorometric procedure for determination of total aflatoxins in peanuts, peanut products, almonds, apricot seeds, pistachios, hazelnuts and cashews (VICAM AflaTest method);
- ✧ Fluorometric procedure for determination of total aflatoxins in cereal products and corn (VICAM AflaTest method);
- ✧ Fluorometric procedure for determination of total aflatoxins in cannabis flower (VICAM AflaTest method).

Division for Metal Testing

According to the National Program for Preventive Health Care (sanitary-health section), this Division tests the level of toxic metals in food products, mineral composition of food with special nutritional properties, determines the presence of some toxic metals (As, Al, Hg, Ni) in waters, cannabis flower, medicines and cosmetics. All these tasks are performed as a routine, legal obligation, at the request of a user or upon indications.

One of the project activities of the Division includes analysis of toxic metals in biological material.

The Division also performs regular monitoring of the level of heavy metals in food products available in the wider trade network. At the same time, heavy metals in seasonal vegetables and fruits available at the green markets are examined twice a year. These monitoring activities are organized by IPH-Skopje, Ministry of Health of RNM and Food and Veterinary Agency of RNM.

The Division for Metal Testing has been accredited since 2006, according to ISO 17025 standard and successfully maintains the accreditation of all methods.

The Division has the following analytical equipment:

- ✧ Microwave digestion system ETHOS UP
- ✧ ICP MS
- ✧ GFAAS
- ✧ FAAS
- ✧ Mercury Analyses system FIMS 100.

The professional team includes specialists in sanitary chemistry, a master in chemistry, a graduate engineering technologist, a medical laboratory technician specialized in a chemical-biochemical laboratory.

Division for Radiation Protection

The competence of the Division for Radiation Protection is based on the following laws: Law on Health Care, Law on Public Health and Law on Protection from Ionizing Radiation and Radiation Safety.

These laws define obligations and tasks of the Institute for Public Health of RNM, Division for Radiation Protection, for protection of the population from the harmful consequences of ionizing radiation.

For the realization of the tasks arising from the relevant laws in the protection against ionizing radiation, the Division is composed of three units:

The Dosimetry Unit performs the following tasks and analyses:

- ★ Personal dosimetry of subjects who are occupationally exposed to ionizing radiation;
- ★ Assessment of the risk of radiation exposure at workplaces when using sources of ionizing radiation and radioactive materials;
- ★ Assessment of the degree of exposure of the population and occupationally exposed subjects,
- ★ Quality control of x-ray devices in medical diagnostics and veterinary medicine,
- ★ Training of interested parties in the field of radiation protection and safety, and
- ★ Dosimetric measurements at border crossings as a measure to prevent proliferation of radioactive and nuclear materials on the territory of the Republic of North Macedonia.

The Calibration Unit performs:

- ★ Calibration of instruments/dosimeters for environmental and personal monitoring used in radiation protection in medicine and industry.

The Radioecology Unit performs the following tasks and analyses:

- ★ By applying analytical methods, it detects and quantifies the contents of naturogenic and anthropogenic radionuclides in various samples (food, water, air, building materials, etc.),
- ★ Continuous active and passive monitoring in the environment of the naturogenic radionuclides Radon (Rn222) and Thoron (Rn220) with special emphasis on schools in RNM, and
- ★ Continuous monitoring of ambient external gamma radiation throughout the entire territory of RNM.

In order to fulfill these tasks, highly qualified staff is employed in the Division, whose expertise is continuously upgraded by constant active participation in additional trainings, training courses, seminars in the areas of interest both in the country and abroad, most often organized by the International Atomic Energy Agency in Vienna (IAEA).

From a technical point of view, the Division is adequately equipped with modern equipment which characteristics meet the parameters imposed by the technical standards.

The high professional competence of the employed in the Division in the field of ionizing radiation protection is confirmed by the fact that the laboratory is a full member of:

- ★ The World Network of Secondary Standard Dosimetry Laboratories (SSDL) of the International Atomic Energy Agency and the World Health Organization,
- ★ European Radiation Dosimetry Laboratories – EURADOS,
- ★ European network for continuous monitoring of ionizing radiation in the external environment – EURDEP, and

- ★ Network of radiometric laboratories of the International Atomic Energy Agency - ALMERA.

The Division collaborates with several international institutions and organizations being involved in their activities, such as:

- ★ Realization, coordination or participation of Division's experts in the projects of the International Atomic Energy Agency in Vienna (IAEA),
- ★ Cooperation with the Research Center of the European Commission, JRC Center, Ispra, Italy,
- ★ Membership in the expert group of NATO, Brussels, etc.

The cooperation with the International Atomic Energy Agency (IAEA) resulted in implementation of several projects for technical and technological upgrading as well as additional professional development of Division's staff:

- ★ Project for the establishment of a modern system for personal dosimetry with the introduction of thermoluminescent personal dosimeters (TLD) as a replacement of the old system with film dosimeters, its upgrade with the introduction of a fully automated system for reading personal dosimeters, through the projects: MAK/9 /002, MAK/9/003 MAK/6/020,
- ★ Project for the establishment of a calibration laboratory for calibration of instruments/dosimeters in radiation protection as well as its additional upgrade for calibration of instruments used in diagnostic quality control, through the projects: MAK/1/002 and MAK/6/012,
- ★ Project for the establishment of capabilities for sustainable continuous registration of external gamma radiation with corresponding improvement of the system for sampling, monitoring and control of contaminants in the environment, including Radon (Rn222) and Thoron (Rn220), as well as a new ongoing project in order to increase the technical capabilities for environmental monitoring, through the projects: MAK /7/002 and MAK7/003.

Most of the methods by which the Division performs tests/calibrations are accredited on the basis of ISO17025 competency standard, starting with ISO17025/2006 standard and subsequently re-accredited to ISO17025/2018.

Based on this standard and by application of appropriate technical standards, the laboratory has accredited the following methods:

Dosimetry unit:

- ★ Estimation of the personal dose equivalent from external exposure to ionizing radiation with thermoluminescent dosimeters for personal or environmental monitoring
Hp(10) and Hp(0.07)
With technical standards: IEC 62387:2012 and IAEA GSG-7:2018

Calibration unit:

- ★ Standard dosimeters in the field of radiation protection for the air Kerma K_{air} for gamma and x-ray radiation,
- ★ Dosimeters in the field of radiation protection for Ambient dose equivalent $H^*(10)$ for gamma and X-ray radiation,
- ★ Active radiation protection dosimeters for personal monitoring of Personal Dose Equivalent $H_p(10)$ and $H_p(0.07)$ for gamma and X-ray radiation,

- ★ Irradiation of passive dosimeters in the field of radiation protection for personal monitoring for Personal dose equivalent $H_p(10)$ and $H_p(0.07)$ for gamma and X-ray radiation,
- ★ With Technical Standards: ISO 4037/I/II/III/2019(E) and ISO29661/2017.

Radioecology Unit:

- ★ Measurement of radioactivity in the environment – Soil – Part Three: Method for testing gamma-emitting radionuclides by gamma spectrometry.
With the technical standard: ISO18589-3:2015,
- ★ Water quality - Determination of radionuclides activity concentration - High resolution gamma spectrometry method
With the technical standard: ISO 10703:2021-
- ★ Water quality - Measurement of gross alpha activity in non-saline water – Thick-source method
With the technical standard: MKS ISO 9696:2018
- ★ Water quality - Measurement of gross beta activity in non-saline water – Thick-source method
With the technical standard: MKS EN ISO 9697:2019



8. *SECTOR FOR ADMINISTRATIVE AFFAIRS AND LOGISTICS*

Head: Juliana Tomanovska, grad. econ.

Activities of the Sector for Administrative Affairs and Logistics

- ★ prepares and legally formalizes and elaborates the drafts of all internal general acts of the Institute;
- ★ develops and legally formalizes all decisions, solutions and conclusions of the management bodies of the Institute;
- ★ monitors and implements legal regulations of general importance and gives legal opinions regarding the accurate alteration/adjustment of legal and other regulations;
- ★ prepares internal regulations for personal data protection and documentation for technical and organizational measures to ensure privacy and protection of personal data processing and harmonization of the internal regulations for protection of personal data with the documentation for technical and organizational measures to ensure privacy and protection of personal data processing with the law and with the regulations adopted on the basis of the law on personal data processing;
- ★ participates in the development of measures and making decisions related to processing of personal data;
- ★ performs all administrative and legal work in the Institute;
- ★ performs all administrative tasks related to the implementation of the procedure for determining the workplace violations and the material responsibility of the employed in the Institute;
- ★ performs all work-related tasks;
- ★ takes care of fulfillment of workers' rights in relation to health care and social insurance;
- ★ mid-term planning of necessary resources and preparation of annual employment plans in accordance with established priorities and policies for employment in a university clinic;
- ★ implementation of procedures for employment, promotion and monitoring of vertical and horizontal mobility of employees;

- ★ keeps personal records and manages employees' personal data;
- ★ prepares decisions, solutions, contracts, agreements related to fulfillment of the rights and duties of employees in accordance with the Law and by-laws and collective agreement;
- ★ ECHR management;
- ★ assessment of needs for training and professional development of licensed health workers and unlicensed employees; generic and specific thematic issues and preparation of an annual program for professional development of administrative officers and public service providers;
- ★ implements a procedure for evaluation of administrative officers and public service providers;
- ★ conducts surveys and analyses on job satisfaction, employee commitment and other aspects and parameters of human resource management that affect productivity or are part of the health facility's accreditation and quality management (ISO, CAF);
- ★ carries out work in the field of national defense and civil protection in accordance with legal regulations and general acts of the Institute in this field;
- ★ litigates unpaid claims of the Institute and other legal disputes;
- ★ performs technical preparations for the sessions of the management bodies, that is, performs all administrative-related tasks of these bodies;
- ★ takes care of the intended use of the working premises;
- ★ manages the archive of the Institute according to the regulations of office work, takes care of receiving, opening, filing, sorting, and sending mail;
- ★ registers, archives and keeps the acts, that is, takes care of the administrative archive of the Institute;
- ★ takes care of maintaining the cleanliness of the working premises of the Institute, correct functioning of the telephone switchboard, the fire service for securing the buildings and property of the Institute, as well as implementation of house rules in the Institute;
- ★ design, installation, maintenance and development of the information system;
- ★ other tasks for the needs of the Institute that are related to the information system and technology;
- ★ organizes and coordinates with the work of other working units related to the use of vehicles, transportation of materials and workers when they travel on official trips with the means of transportation of the Institute, i.e., calculation and control of the use of means of transportation and the fuel and oil consumption;
- ★ takes care of maintenance and repair of the building, auxiliary buildings of the Institute, working premises, installations, appliances and devices and other basic assets and inventory;
- ★ analysis and preparation of a plan for the type and scope of services necessary for providing finances from the Health Insurance Fund for normal functioning of the Institute;
- ★ prepares reports at the request of the Health Insurance Fund and Ministry of Health;
- ★ daily treasury management;
- ★ takes over and controls daily turnover and transfers it into the bank;
- ★ controls the accuracy of invoices that are paid through the treasury of the Health Insurance Fund;
- ★ implementation of all types of payments through the treasury of the Health Insurance Fund;

- ★ uploading the financial plans as well as repurposing them in the Health Insurance Fund treasury;
- ★ monitors the execution of the agreed compensation/financial plan;
- ★ salary preparation and payment to employees;
- ★ issues valid documentation for the amount of net salary for the needs of employees;
- ★ performs other tasks in the field of payment transactions;
- ★ accounting, financial and material operations;
- ★ prepares monthly invoices for the services given to the Health Insurance Fund as well as of invoices to all other entities that use the services of the Institute;
- ★ recording of claims and their collection as well as recording of liabilities and their payment;
- ★ keeps records of materials and small inventory and their utilization;
- ★ monitors income realization and execution of expenses;
- ★ compilation, receipt, liquidation and control of accounting documents;
- ★ prepares periodic and final accounts;
- ★ prepares various financial reports depending on the requirements;
- ★ accounting recording of the entity's basic assets;
- ★ calculation of depreciation and revaluation;
- ★ adjustment of the funds and sources of funds of the bookkeeping with the actual situation;
- ★ organizes the procedure for the annual inventory of materials, small inventory and basic assets and comparison of the accounting and actual situation;
- ★ provides professional assistance in preparing income and expenditure calculations;
- ★ monitoring and application of legal regulations in the field of accounting, material and financial operations;
- ★ performs other tasks in the field of accounting
- ★ coordination of the preparation of the Public Procurement Plan, which should be in line with the financial plan approved by the Health Insurance Fund;
- ★ prepares the tender documentation in coordination with the competent persons of the departments and sectors;
- ★ prepares the necessary acts from the beginning of the procedure and based on the report of the procedure carried out in accordance with the Law on Public Procurement (Decisions on public procurement, decisions on the selection of the most favorable bidder, selection notices to economic operators, preparation of contracts for public procurement and others necessary documents);
- ★ provides assistance and coordination to the Public Procurement Commission;
- ★ updating the necessary documents in the Electronic Public Procurement System of the Public Procurement Bureau;
- ★ prepares orders and monitors depletion in accordance with public procurement contracts;
- ★ participates in the preparation of the budget; preparation of the public procurement plan; and implementation of the procurement plan;
- ★ monitors the legal regulations in the field of procurement and their correct/adequate application;

- ✧ monitors the process of signing contracts and their implementation according to the law on public procurement;
- ✧ participates as a member of the commission in the procedures for awarding a contract for public procurement with an estimated value over 130,000 euros in denar equivalent value for goods and services and over 5,000,000 euros in denar equivalent;
- ✧ prepares the necessary acts based on the report of the conducted procedure;
- ✧ publishes a negative reference in Electronic Public Procurement System;
- ✧ provides guidelines and instructions to the contracting authority regarding handling the appeal procedure in cooperation with the commission;
- ✧ takes care of the files from procedures carried out in accordance with the regulations for office and archival work.

The Sector for Administrative Affairs and Logistics also includes the competences of the auxiliary services performed by the auxiliary technical personnel employed at the Institute:

- ✧ technical maintenance of the equipment;
- ✧ securing the facility;
- ✧ cleaning and hygiene maintenance in the facility;
- ✧ other things.

The Sector consists of:

- ✧ Division for Legal Affairs and International Cooperation
- ✧ Division for Accounting and Finance
- ✧ Division for Public Procurement
- ✧ Division for Commercial Affairs and Collection of Receivables
- ✧ Division for Human Resources, Public Relations and Logistics

SOME OF THE PROJECT ACTIVITIES

Name of project	Donation, organization, other	Period/year of activity
ESPAD 2019	EMCDDA	2018/2019
Bebbo апликација	УНИЦЕФ	2022
Bebbo application	UNICEF	2022
Internet search on drugs in RNM	EMCDDA	2021/2022
Parenting Strategy	UNICEF, MH	2022
Avian and Pandemic Influenza Surveillance and Response by National Health Authorities Outside the United States	CDC through WHO and SECID	2017/2021
PRO-METROFOOD	EU	2017
INHERIT	EU	2016
HMB4EU	EU	2020
Equal life	EU	2020
Behavioral study – COVID-19	WHO	2021
A survey of knowledge, attitudes and practices (KAP) related to influenza vaccination among healthcare workers in the Republic of North Macedonia.	RKI in collaboration with SECID	2019
Technical and operational support in the establishment of an Emergency Operational Unit of the Ministry of Health of RNM within the framework of the establishment of Operational Emergency Centers in public health	WHO	2020
Implementation of PHEOC in Macedonia	WHO, RKI	2020/2021/2022
Sero-epidemiological study on COVID-19 virus infection in the general population in the Republic of North Macedonia, stratified by age	WHO	2021/2022
Building capacities for epidemiological monitoring of COVID-19 cases and their contacts and communication about Covid-19 in the Republic of North Macedonia	WHO, RKI	2021
Capacity mapping research on	PIVI (Partnership for Influenza Vaccine Introduction)	2019
"cold chain" for storage and transport of vaccines used in the Republic of North Macedonia	PIVI (Partnership for Influenza Vaccine Introduction)	2019
Attitudes of parents regarding measles vaccination - the CAP study	WHO	2019/2020
Operationalization of PHEOC and networking with regional and local units of EOS in Macedonia	WHO	2022
MAK 5009	IAEA (International Atomic Energy Agency)	2021-2022
European Childhood Obesity Surveillance Initiative (COSI)	MH and WHO	2010, 2013, 2016, 2019,2022

