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**STRATEGY
ON BIOMEDICAL (HEALTHCARE)
WASTE MANAGEMENT**

Former Yugoslav Republic of Macedonia

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ABBREVIATIONS

BCRC	Basel Convention Regional Centre
GP	General Practitioners
DFID	Department for International Development
DPSIR	Drivers, Pressure, State, Impact, Response (Methodology)
EU	European Union
HCWM	Health Care Waste Management
HCRW	Health Care Risk Waste
HCW	Health Care Waste
HIs	Healthcare Institutions
HIF	Health Insurance Fund
IPPC	Integrated Pollution Prevention and Control
IARC	International Agency for Research on Cancer
LSG	Local Self-Government (= Municipalities)
MEIC	Macedonian Environmental Information Centre, MEPP
MEPP	Ministry of Environment and Physical Planning
MoH	Ministry of Health
MoTC	Ministry of Transport and Communication
MAFWE	Ministry of Agriculture, Forestry and Water Economy
MSW	Municipal Solid Waste
NWMP	National Waste Management Plan
NEAP	National Environmental Action Plan
OGRM	Official Gazette of the Republic of Macedonia
PE	Public Enterprise
PHC	Primary healthcare
RIHP	Republic Institute for Health Protection
SBC	Secretariat of the Basel Convention
SCI	State Communal Inspectorate
SEI	State Environmental Inspectorate
SSHI	State Sanitary and Health Inspectorate
SVI	State Veterinary Inspectorate
TA	Technical Assistance
UNEP	United Nations Environment Programme
WHO	World Health Organisation

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SUMMARY

Background

Former Yugoslav Republic of Macedonia as an EU candidate country has a goal to transpose and implement a number of EU directives. Many of them pose serious challenges, not only in relation to the investment cost but also in relation to the skills needed to prepare and implement projects. Health Care Waste Management (HCWM) is one of the most challenging sectors, and at the same time, one of the top priority sectors of the country.

Within the Sub-Programme "Environmentally Sound Management of Basel Convention Priority Waste Streams: Biomedical and healthcare wastes" enabled by the support of the Basel Convention Regional Centre Bratislava (BCRC Slovak Republic), Secretariat of the Basel Convention (SBC) and UNEP, a "Strategy on the management of the biomedical (healthcare) waste" has been developed for the territory of Former Yugoslav Republic of Macedonia. This project is for the benefit of the Ministry of Environment and Physical Planning - MEPP, meeting in the same time the objectives of the Business Plan of BCRC for 2005-2006. In the following lines of this report the main project outcomes are discussed.

The project covered National analysis on HCWM including all relevant streams according to the existing classifications and handling methods. The existing legal framework, its gap analyses and present enforcement have been considered. In addition, highlights on the main national and local stakeholders including the HCW generators have been given in the report.

Stakeholders and legal framework

Formulation of policies, drafting and law enforcement in the area of the HCWM is shared between several ministries: Ministry of Environment and Physical Planning (MEPP), Ministry of Health (MH), Ministry of Agriculture, Forestry and Water Economy (MAFWE) and the Ministry of Transport and Communications (MTC). Supervision / inspection are also conducted by a number of inspection units, operating under auspices of the mentioned Ministries (State Sanitary Inspectorate - Ministry of Health, State Environmental Inspectorate - Ministry of Environment and Physical Planning, State Veterinary Inspectorate - Ministry of Agriculture, Forestry and Water Economy), while gaps and overlaps appear due to the either lack of clarity regarding the split of responsibilities in the laws, or because the institutions lack coordination. Another obstacle is the lack of experience on this rather new competence being driven by the EU accession. It can be concluded that the present institutional capacity to carry out the policy formulation, monitoring / inspection, record keeping, reporting and enforcement of the legislation is relatively low at present.

From the legal point of view it is assessed that the existing (and pending) laws and regulations do provide a good base for the management and treatment of HCW, however, if the national system would comprise of treatment of HCW based on incineration, the provisions of the **Directive on Incineration of waste (2000/76/EC)** of December 2000 must be transposed into national legislation in the near future. A detailed "Guideline on Management of HCW", comprising all necessary actions in order to comply with the current and pending HCW legislation is required as well.

Present HCWM practice

Municipal, and preferably in the future - inter-municipal authorities, are responsible for collection, treatment and final disposal of the municipal solid waste (MSW). Since no special treatment is provided for HCW in the municipalities except for Skopje, it is handled as MSW at present. The system for transportation, treatment, and disposal of such HCW is normally considered a responsibility of the local solid waste authorities, although the Law on Waste Management does not allow this practice any longer. It points to a conclusion that the primary objective of the system is to create conditions for a separate collection of the HCW by licensed operators.

As mentioned above, the Skopje system is quite specific. Public Enterprise "Komunalna Higijena" is established and owned by the City of Skopje. The company deals with waste collection (mixed

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municipal waste and separate collection of HCW) in the urban area of Skopje. The company operates the "Drisla" Landfill (for disposal of mixed municipal waste) and the incinerator for HCW, which is installed at the premises of the mentioned landfill. The amount of HCW received at the landfill is measured at the entrance using the landfill weigh-bridge. Amount of municipal types of waste received at Drisla Landfill for disposal is around 180,000 tons/year. It comprises of the HCW collected in Skopje (by the PE "Komunalna Higijena") and Kumanovo (collected and transported to Skopje by the Health Care Institute from Kumanovo).

An essential problem with HCW in Former Yugoslav Republic of Macedonia is that although the existing incinerator by its capacity allows for the disposal of all hospital waste generated, about 65% of the hospital wastes are deposited in open, uncontrolled municipal dumps resulting in serious health and environmental risks. In addition, the incinerator is not equipped with a gas flue cleaning system which causes significant environmental and health risks. Due to the high investment costs for the upgrading, but also the high operational costs including expenditures for the flue gas cleaning unit, the existing incinerator cannot be used in the future if the EU Directive 2000/76/EC must be met. Thus, present HCW treatment via incineration may not serve a permanent solution.

There is also an incinerator at the Faculty of Veterinary Medicine which is aimed at burning animal carcasses and other animal by-products generated in the Faculty in accordance with EC Regulation 1774/2002 (previously Regulation 90/667/ECC) on health rules concerning animal by-products not intended for human consumption; it cannot be used for other types of waste, including the HCW.

Concerning the in-site treatment, it can be said that the only internal disinfection of HCW is done in the Institutes for Health Protection as well as in Departments for Infectious Diseases located in the Clinical Centre-Skopje and in General Hospitals throughout the country. Internal treatment is carried out in small autoclaves and covers only HCW such as sharps, culture plates and small glass tubes with blood samples.

HCW generation

According to the Macedonian Environmental Information Centre, which is the focal point for processing of the environmental data in MEPP, no data on waste, being hazardous or non-hazardous, so far are being received on a regular basis. MEIC expects that the first annual reports from waste generators and waste treatment and disposal facilities will be received at the start of 2008. By the end of the project the MEIC did not receive substantial number of such reports. The limited responding to the legal requirement is seen as a result of the lack of its stringent enforcement, but also as a consequence of the weak capacities of the hospital's staff to introduce the reporting system.

To estimate the present HCW generation the sources of the second National Environmental Action Plan (NEAP II) and the National Waste Management Plan 2006-2012 have been used. Both come up with the figure of 800-1000 tons/year. Out of this amount about 350-360 tons/year is incinerated in Skopje.

The input data for the designing of the national health care waste management system have been collected throughout the national survey being conducted in January 2007. The National Survey confirmed the estimated figure (927 tons/year), however, better understanding of the participation of various sources in the overall generation has been obtained, as well as more data on the composition of the HCW had been acquired

The present financing of the HCW management is considered as important as the technical issues. Therefore, the tariffs for the various users of the system on Skopje (public and private Health care facilities in Skopje and Kumanovo) have been analysed in combination with the present budget allocations for the health care sector (e.g. Health Insurance Fund). It appeared that the present tariffs, being high for the area covered by incineration, and low for HIs outside the system have not been set transparently. The root of problems seems to be the unclear institutional set-up of the Skopje HCWM system in which the contractual arrangements between the Ministry of Health and the City of Skopje are

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obsolete. It is expected that amendments of present laws, or issuing a new regulation (e.g. methodology on setting tariffs) and/or involvement of a regulatory body is the start for the solution of the problem.

Future scenarios

Following above described analyses, a set of recommendations are formulated in the strategy and accompanied by three scenarios for the countrywide HCWM system.

One of the main strategic and financial questions is whether for the final disposal of the HCW, generated in the hospitals and clinics in Former Yugoslav Republic of Macedonia, only one central incinerator (i.e. at the Drisla landfill) is the optimal solution, or that also establishment of smaller regional incinerators is a more cost effective solution.

Therefore a few logistical and operational scenarios were developed, in order to assess the various options. In the total plan also the feasibility of in-hospital treatment options - e.g. autoclaving / disinfection-sterilisation - for certain HCW streams have been roughly assessed.

The following three development scenarios for treatment of HCW have been selected for further investigation in the present HCW Strategy:

- Scenario 1: Central treatment in one incinerator located in or nearby Skopje;
- Scenario 2: Central treatment in one autoclave located in Skopje;
- Scenario 3: Decentralised treatment in three autoclaves located in Skopje, Bitola and Stip.

The collection / transport and treatment options have been analysed in light of the (i) distribution of generating sources throughout the country, (ii) the amount / composition of the HCW for disposal and the (iii) advantages / disadvantages of the centralized versus decentralized systems and the treatment technologies.

Treatment technologies

The incineration is a proper solution for a broad range of HCW categories, provided that the gas flue is treated properly. There isn't a legal base for the emission standards for incineration. The incineration is costly, requires qualified staff and the residues have to be disposed at a landfill for hazardous waste, which does not exist in Former Yugoslav Republic of Macedonia. In addition treatment of HCW based on incineration is subject to obtaining of "A" integrated environmental permit and an Environmental Impact Assessment (EIA) implementing in accordance with the Law on Environment. Acceptance of the population living nearby the incinerator is to be obtained through the public participation, following the above processes.

It can be assessed that about 90-95 per cent of the yearly amount of HCW in a given area can be treated in appropriate autoclaves. The remnants (mainly pharmaceuticals and chemicals) must be collected separately and sent for treatment elsewhere in dedicated facilities (e.g. at a national centre for treatment of the much larger amounts of hazardous waste generated by industry and households). Also the biological (pathological) waste, depending on the chosen autoclave, could be treated more appropriately by incineration or by burial at cemeteries, e.g. because of ethical considerations. An autoclave will produce a minor amount of wastewater in the form of condensed steam when the autoclave is evacuated following the sterilisation cycle. In addition, autoclaving requires B integrated permit, which is less stringent than the A integrated permit, being compulsory for incinerators.

National Workshop

The main findings of the Strategy have been presented at the national Workshop. The participants have expressed various concerns with respect to the prospects to organize the HCWM in line with the Strategy's recommendations. The next may be distinguished as the most important:

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- The transition between the present practice where the HCW is handled as a municipal waste and the future HCWM in line with the EU standards requires applying of subsequent measures, combining the penalties and incentives
- Above all, the political will is required to implement them
- Another important tool to be used is the awareness raising; target groups are not only the public, the inspectors and the health care practitioners, but the high level decision making officials; they are the key stakeholders to pursue changes
- The national stakeholders should enhance the HCWM planning at regional and hospital level; the regional planning is required to determine the hierarchy of the collection schemes (collection and storage points) and the secondary transport to the disposal facility (incinerator or the autoclave(s)).
- The plans must address the financing of the operations
- The drafting and implementation of hospital's plans should be driven by highly competent waste managers;
- HCWM practice within hospital's premises should be subject to regular inspections
- Participants did not favour the proposal to treat the HCW by incineration
- Between the central (one autoclave) and decentralized (three autoclaves) option they preferred the latter. Final decision must be made by the Government

Recommendations and the Action Plan

The elements of the Action Plan have been set based on the project analyses and the recommendations of the workshop's participants. These are outlined below.

Prior to the establishment of the national system, the first step towards the improvement of the present practice at generator's level will be development of management plans for large Health Care facilities (as the threshold for planning and reporting has been set in the legislation at 50 kg/year of hazardous waste generated) in both the public and private sector. Based on Plans the internal monitoring and reporting must be carried out.

Next step would be carrying out of specific trainings and campaigns aiming to raise awareness and capacity on HCWM throughout the country. Crucial is to train the hospital Waste Managers and the inspectorates.

At present two ministries are competing for the leadership role in the HCWM - the Ministry of Environment and Physical Planning and the Ministry of Health. Further, the responsibility issues are complicated by the position of the Operator of the existing incinerator - the City of Skopje Public Enterprise "Drisla", which is operating the incineration under some formerly set contracts being nowadays obsolete and outside the present law approximated with the EU. With the Scenarios 2 and 3 there is a possibility to abandon present practice (and especially to exclude the PE "Drisla" from the institutional set-up). Prior to selecting the preferred option a political will to change the situation must be demonstrated. During a broad stakeholder communication the final decision on the HCWM scenario should be made, aiming at setting the institutional and financial pre-requisites for financing of the entire system. It is regarded a follow-up of the present project.

After a political decision is taken, the regional plans including the technical planning (collection, transport and disposal) as well as the financing schemes (including the user charges) should follow. Upon the fundraising supported by national allocation of the co-financing, there should be "elected" a nationally recognized owner of procurements related to an improved HCWM system.

In order to set conditions for implementation of the Health Care Waste Management Strategy stakeholders should assign staff and allocate resources; of utmost importance is the institutional reform whereas financing of in-premises and beyond premises health care waste handling is crucial.

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Taking over the entire system by the HIs would further contribute to setting more equitable and transparent tariffs. Private sector can be invited to take part presumably in the "external" collection and transport; an option for consideration is outsourcing of the HCW treatment to a private operator.

1 BACKGROUND

1.1 Introduction

Health Care Waste (HCW) e.g. pharmaceuticals, etc. is a small fraction of urban municipal waste. Infectious or hazardous hospital waste represents only a small part of total HCW; yet, because of ethical questions and potential health risks, it is a focal point of public interest.

Experience from EU Member States demonstrates that once HCW has been effectively treated it poses no greater hazard to the environment than municipal waste, if proper management practices are applied. The mismanagement of healthcare waste poses risks to people and the environment. Healthcare workers, patients, waste handlers, waste pickers, and the general public are exposed to health risks from infectious waste (particularly sharps), chemicals, and other special HCW. Improper disposal of special HCW, including open dumping and uncontrolled burning, increases the risk of spreading infections and of exposure to toxic emissions from incomplete combustion. The main sources of illness are injuries with used needles leading to blood-borne infections, which can cause hepatitis and HIV. There are, however, numerous other diseases which could be transmitted simply by contact with HCW.

According to the Constitution from 1991, Former Yugoslav Republic of Macedonia is defined as a sovereign, independent, democratic and social state. One of the fundamental values defined in article 8 of the Constitution that concerns the protection of the environment is the humanization of space and the protection of environment and nature. This fundamental value has provided new frames for managing the protection and care of the environment. Furthermore, the Constitution prescribes certain responsibilities and rights in respect of the protection of the environment in Chapter II, Article 43, guaranteeing the right of everyone to a healthy environment but also provides a responsibility that each person is obliged to promote and protect the environment. In addition, Former Yugoslav Republic of Macedonia has an obligation to provide all necessary conditions for exercising the right of citizens to a healthy environment. Therefore, the proper handling of the Health Care Waste is crucial for the protection of the environment and human health, thus efforts to improve the present inappropriate situation in the field will follow the basic human rights for all the citizens in the country.

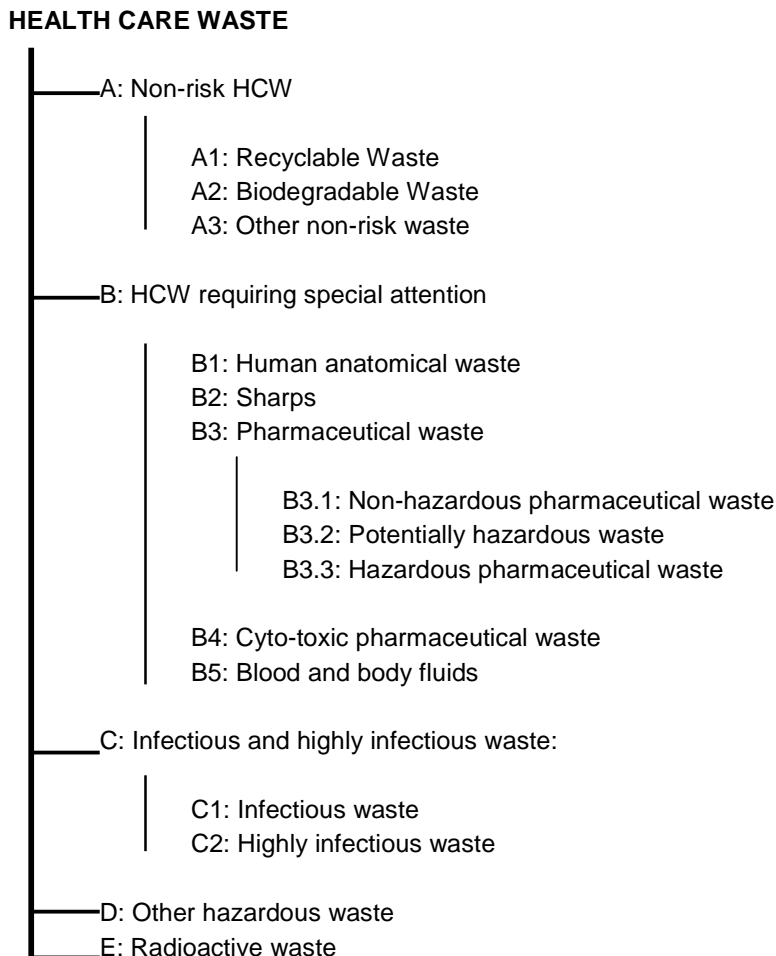
1.1.1 Definitions and classification of health-care waste

Health-care waste includes all the wastes generated by medical activities. It embraces activities of diagnosis as well as preventive, curative and palliative treatments in the field of human and veterinary medicine. In other words, all wastes produced by a medical institution (public or private), a medical research facility or a laboratory are considered health-care waste.

Health Care Waste is considered a priority waste stream in Former Yugoslav Republic of Macedonia, along with municipal and hazardous waste (to the latter it actually belongs as a fraction).

According to the Technical Guidelines on Environmentally Sound Management of Biomedical and Health-Care Waste provided by the Conference of the Parties to the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal (170 Parties in 2008), health-care waste are classified as follows (see Figure 1):

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Figure 1 Health Care Waste Streams

The generally accepted definition of health care risk waste is the one being produced in healthcare or similar activities that poses a risk of infection or waste that may prove hazardous and or which has the following characteristics:.

(a) any waste which consists wholly or partly of human or animal tissue, blood or other bodily fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming into contact with it; and

(b) other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it.

1.1.2 Objectives of the present Strategy on Health Care Waste

Former Yugoslav Republic of Macedonia as an EU candidate country has a goal to transpose and implement a number of EU directives. Many of them pose serious challenges, not only in relation to the investment cost but also in relation to the skills needed to prepare and implement projects. HCWM is one of the most challenging sectors, and at the same time, one of the top priority sectors of the country.

National analysis on HCWM should cover all relevant streams, as well as handling methods in accordance with the Directive 91/689/EEC on hazardous waste and other related EU directives. The EU

List of Wastes¹ is to be applied to allow for harmonisation of information on waste generation and management as it is the case in the EU and to provide an application of the common EU-wide waste classification system for hazardous and non-hazardous waste. The national legal framework should be taken into consideration. The World Health Organization (WHO) classification should be taken into consideration as well.

The importance of the improved management of the Health Care Waste is emphasised in the following strategic documents produced on a national level:

- National Environmental Health Action Plan, 1999 (NEHAP);
- National Environmental Action Plan II, 2006 (NEAP II);
- DPSIR Report on Waste, 2005 (input to NEAP II);
- National Waste Management Plan 2006-2012 (although not formally adopted yet);
- Health Systems in Transition for Former Yugoslav Republic of Macedonia, 2006;
- Public Investment Programme 2006-2008.

In previous analyses it was found that a variety of methods were used by the medical facilities to dispose their wastes including burning, burial, dumping, but in most cases removal of mixed HCW by municipal bins took place. The waste disposal practice was found to be quite unsafe, and both clinical and non-clinical wastes were found to be thrown together with the hazardous waste components (since collection was carried out for mixed waste).

Within the Sub-Programme "Environmentally Sound Management of Basel Convention Priority Waste Streams: Biomedical and healthcare wastes" enabled by the support of the Basel Convention Regional Centre Bratislava (BCRC Slovak Republic), Secretariat of the Basel Convention (SBC) and UNEP, a "Strategy on the management of the biomedical (healthcare) waste" is to be developed for the territory of Former Yugoslav Republic of Macedonia. This project takes into account the needs expressed by the national authorities (the Ministry of Environment and Physical Planning - MEPP in particular) concerning the healthcare management that are contained in the Business Plan of BCRC for 2005-2006.

The project contributes to reaching the following priority fields of the Strategic Plan for the implementation of the Basel Convention adopted in the COP 6/1 decision in 2002:

Field (a): Prevention, minimisation, recycling, recovery and disposal of hazardous and other wastes subject to the Basel Convention, taking into account social, technological and economic concerns

Field (e): Improvement and promotion of institutional and technical capacity-building, as well as the development and transfer of environmentally sound technologies, especially for developing countries and countries with economies in transition

Field (h): Co-operation and partnership at all levels between countries, public authorities, international organisations, the industry sector, non-governmental organisations and academic institutions

A review of HCW management systems is to be performed to understand (a) the various handling and disposal procedures in Former Yugoslav Republic of Macedonia, (b) the knowledge and awareness of individuals involved in HCW generation, handling and disposal, and (c) the potential impacts of the waste stream on both human health and the natural environment.

The purpose of the Strategy is to provide direction for action of involved stakeholders.

With regards to the country specifics, this project is aimed to achieve the following specific objectives:

¹ Source: "Hazardous waste generation in EEA countries", Topic Report 14/2001, European Environment Agency.

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- To obtain and analyze information on the collection, treatment, handling, hauling, and disposal of HCWs;
- To determine the level of knowledge and awareness of individuals involved in Health Care Risk Waste handling (from the source of generation to the final disposal destination);
- To highlight the potential impacts that HCWs pose to both human health and the natural environment due to improper disposal and management techniques;
- To direct further stakeholder action.

In addition, the national strategy for HCW management should:

- Reflect priorities within healthcare facilities for treatment and disposal of healthcare waste.
- Set goals for and means of monitoring of infection control and environmental protection.
- Propose choice of technology for packaging, transportation, treatment, and disposal.
- Prioritize central or decentralized treatment and disposal.
- Reflect distribution of responsibility in the sector between national, regional and local governments.
- Make recommendations on private sector involvement.
- Propose an action and investment plan for implementing an improved HCW management.
- Propose mechanisms for financing healthcare waste management.
- Propose guidelines for HCW management training programmes at facility and municipal/regional level.

2 HEALTH CARE WASTE MANAGEMENT - GENERAL PRACTICE

Project analyses cover the existing legal environment concerning the HCWM, its gap analyses and present enforcement, the main national and local stakeholders as well as an overview of the health care sector aimed at identification of all HCW generators.

2.1 Legal Framework (horizontal and vertical laws)

The Government of Former Yugoslav Republic of Macedonia has adopted two framework legislative instruments for implementation of the basic principles for protection and care of the environment including waste management, the **Law on protection and promotion of the environment and nature** in 1995 and the **Law on waste** in 1998. According to the Law on protection and promotion of the environment and nature, the Government defined the hazardous waste in full compliance with the **Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal**, ratified in 1997.

In 2002, taking into consideration the gaps of the existing relevant legislation compared to the EU requirements, the Government initiated the process of drafting new legislative instruments. A package of 3 legislative instruments was adopted by the Parliament in the period of 2004-2005, including: the new **Law on the Environment**, the new **Law on Waste Management** and the Law on the **Protection of Nature**.

The definition of HCW and provisions regarding management and disposal of HCW, are currently being regulated by the legislative instruments elaborated below:

2.1.1 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (OGRM 49/97)

The Parliament of Former Yugoslav Republic of Macedonia has adopted the Law on the ratification of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal in 1997. According to the principles of the legal system in Former Yugoslav Republic of Macedonia, after the official ratification the international documents become part of the national legislation and have equal legal power as national law.

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted in 1989 and entered into force on 5 May 1992. This environmental treaty strictly regulates the transboundary movements of hazardous wastes and obligates its Parties to ensure that such wastes are managed and disposed of in an environmentally sound manner. The Basel Convention is administered at the national and also at the state level, depending on the contracting Party's legislation. 170 Parties in 2008 had ratified the convention².

The Basel Convention makes specific reference to the control of HCW like sharps, pathological infectious waste, hazardous chemical waste, and pharmaceutical waste in Annex 8:

- Clinical wastes from medical care in hospitals, medical centres, and clinics (Y1).
- Wastes from the production and preparation of pharmaceutical products (Y2).
- Waste pharmaceuticals, drugs, and medicines (Y3), and
- Waste from the production, formulation and use of biocides and phytopharmaceuticals (Y4).

² <http://www.basel.int/ratif/convention.htm>

2.1.2 Law on the Environment (OGRM 53/05)

In the Chapter on Integrated Prevention Pollution and Control the Law on the Environment provides for procedures for permitting companies to set up standards, whose purpose is to limit the influence of pollutants. The Law further sets the legal basis for adopting legislative instruments on procedures, activities, and requirements covering A or B integrated environmental permitting systems. Installations for treatment and processing of hazardous waste (including HCW) waste are to be covered by the permitting system. It must be mentioned that "A" installations are fully in line with the EU IPPC Directive, while the "B" category has been introduced in Former Yugoslav Republic of Macedonia aiming to cover processing facilities below thresholds as under the "A" list. The Law does not address directly the issuing of integrated environmental permits to HCW treating companies or legal persons, but the standards and the limits are determined for hazardous waste in general.

The implications are that the treatment of HCW based on incineration will need an "A" integrated environmental permit. However, the Law sets the basis for regulating other treatment types, e.g. sterilisation in autoclaves requiring permits for processing, treatment and/or storage of waste. The issue is covered in detail in the Regulation on the form and content of the Request and Permit for processing, treatment and/or storage of waste, form and content of the permit and the technical conditions for performing the activity (OGRM 23/07), which is described in the further paragraphs.

2.1.3 Law on Waste Management (OGRM 68/04; 71/04)

The Law on Waste Management defines all types of wastes according to the legislation of the European Union. In article 6, the **HCW is defined as a "waste generated in medical and health institutions** (dispensaries, hospitals, polyclinics and outpatient departments, dental clinics, veterinary stations), which originated as a product of used items and materials during diagnosing, medical treatment and prevention of diseases of in human and animals." In respect of this definition, the Government introduced in the definition of the HCW also the waste of veterinary institutions but at the same time excludes the waste from scientific, developing and researching institutions.

The Law on Waste Management provides the legal base for further regulation by secondary legislation of the following issues:

- Separate handling of hazardous waste
- Mixing of hazardous waste
- Obligations to register and classify hazardous waste

The Law on Waste Management lists the HCW as one of the types of hazardous waste, thus in the Chapter for handling hazardous waste, Sub-chapter for handling specific types of hazardous waste (article 73) is prescribed that the **HCW shall be handled in accordance with the provisions for handling hazardous waste**. In this article the legal basis for two legislative instruments is set as follows:

- Detailed prescription of the **manner of handling HCW, the labeling and forms related to HCW handling, as well as the types of HCW whose processing shall be prohibited**. A draft regulation is being produced recently in cooperation between the Ministry of Environment and Physical Planning and the Ministry of Health. The content of the draft regulation is briefly presented in later paragraphs.
- Regulation on **Conditions for Handling Hazardous Waste and the Manner of Packaging and Labelling the Hazardous Waste**. The Draft regulation is also further explained in terms of its coverage and compliance with the EU Directive on Hazardous waste.

The Law on Waste Management also prescribes in article 86 the **types of waste which can not be accepted in a landfill, including infectious medical and other clinical waste originating form**

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medical and veterinary establishments. It lays down equivalent requirements as the EC Council Directive 1991/31/EC. In article 87, the Law prescribes that the waste which is not acceptable in landfills shall be disposed in an appropriate way, using the operations listed in article 35, that determines the list of disposal operations for all waste streams, including HCW.

In article 126 (and article 132) it is stated that inspection and supervision of generation, selection/segregation and packaging of HCW shall be carried out by the State Sanitary Health Inspectorate (SSHI) in cooperation with the State Environmental Inspectorate (SEI).

2.1.4 Law on Health Protection (OGRM 17/97, 11/02, 10/04, 84/05, 111/05, 65/06, 05/07).

The Law on Health Protection regulates the **health care of citizens, health insurance**, as well as the **organization of health protection**. This Law precisely determines the types of organizations in the health protection system, providing definition for each institution/organisation/centre; this system will be elaborated in detail in the following text, aiming to identify all HCW generation sources.

2.1.5 Law on Veterinary Health (OGRM 28/98)

The Law on Veterinary Health regulates the **health protection of animals, transboundary animal diseases control, veterinary and sanitary inspection and control** etc. The Law also regulates the **residues and waste from animals, facilities for processing animal carcasses, inspection of the disposal of animal residues**, etc.

Bearing in mind the HCW definition in the Law on Waste Management, links are provided through the coverage of the facilities for animal health protection, treatment and final disposal of animals' residues and animal carcasses. In this regard, Law establishes the State Veterinary Inspectorate (SVI) being part of the Ministry of Agriculture, Forestry and Water Economy (MAFWE). Main responsibilities of the inspectorate concern an obligatory veterinary-sanitary control of animals and respective facilities for cattle breeding; in addition, trading with products, raw materials and animal residues, sanitary control for conditions in shops and other shopping places delivering animal origin's products as well as the quality control of livestock food are under the inspectorate's authority.

2.1.6 Law on Sanitary and Health Inspection (OGRM 71/06)

The Law on Sanitary and Health Inspection establishes **competences and organization of the State Sanitary and Health Inspectorate** (SSHI). In this respect the appointment of sanitary and health inspectors, their mandate and the procedures for carrying out the inspection and control are stipulated in detail. The State Sanitary and Health Inspectorate is to carry out inspection and control over the laws and regulations in the area of sanitary-hygiene, epidemiologic and health protection, as well as health insurance. According to the Law on Waste management the SSHI in cooperation with the SEI is responsible for the inspection of the HCW handling.

2.2 Secondary legislation

As it can be seen from the elaborations below, the present framework providing for technical requirements on various steps of handling of hazardous waste streams (including the HCW) is fairly fragmented. Particular pieces of secondary legislation are assessed in detail, giving emphasise on relevant stipulations for handling HCW.

2.2.1 Ordinance on Integrated Pollution Prevention and Control, IPPC (OGRM 89/05)

The Ordinance on Integrated Pollution Prevention and Control establishes regulations concerning (i) the activities that have to be undertaken for implementing new installations, (ii) significant reconstruction of existing installations which already have obtained an integrated environmental permit and (iii) permitting

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for harmonization with the operation plan; the plan contains the time schedule for implementation of envisaged measures to comply with the environmental standards set in the operation plan. **This Ordinance is relevant for the coverage of the "A" group of installations for treatment and processing of hazardous waste i.e. HCW by incineration.** Specific threshold limits for quantities and types of waste covered by the Ordinance are determined in the annexes of the Ordinance.

It is in full compliance with the IPPC Directive.

2.2.2 Regulation on the Procedure for Issuing an Integrated Environmental Permit (OGRM 04/06)

This Regulation prescribes the following: (i) the application form to obtain an "A" integrated permit, (ii) the procedure for submission and requested supporting documentation, (iii) public participation in the process of issuing the A permit, (iv) the procedure for issuing an A permit, (v) the procedure for inspection of the installation, etc. All clinical and veterinarian establishments operating installations for the treatment and processing of HCW (based on incineration) are obliged to obtain an "A" integrated permit.

2.2.3 List of types of waste (OGRM100/04)

The List of types of waste, fully transposing the EU list of wastes (2000/532/EC), establishes the types of waste, which are classified in accordance with the sources of generation and waste characteristics. Group 18 includes the types of waste generated in health care of humans and animals.

2.2.4 Draft Regulation on Conditions for Handling Hazardous Waste and the Manner of Packaging and Labelling the Hazardous Waste

This Regulation, transposing the EU Directive on Hazardous Waste (91/689/EEC), shall determine the **conditions on handling, the manner of packaging and labelling the hazardous waste, as well as the minimal technical conditions of the installations for treatment, processing and disposal of hazardous waste.**

Handling of hazardous waste includes the following activities: collection, selection/segregation, transportation, treatment, processing, storage and disposal. In addition, this document establishes the procedures and forms of labelling and packaging of hazardous waste including the characterization and classification.

This regulation is relevant for the whole chain of operations handling HCW, from the generation up to its final disposal.

2.2.5 Regulation on the Methods and Conditions for Storage of Waste (OGRM 29/07)

This Regulation establishes the **methods and conditions for storage of waste** including also **technical requirements for the storage facilities and their location.** In addition, this Regulation establishes **types of storage, the acceptance procedures of storage, the determination of characteristics of waste that is going to be stored, types and maintaining of containers for storage, protection systems, etc.**

In the Chapter II – Methods of Storage, the procedures for laboratory measurements after the acceptance of wastes at the storage facility, (identification of hazard labelled on the package, risk assessment of unexpected reaction among particular packages, neutralization of risks originating from storage of undesired substances in the same container) are prescribed; in addition, technical requirements for storage of waste are given in this Chapter.

2.2.6 Regulation on the form and content of the Request and Permit for processing, treatment and/or storage of waste, form and content of the permit and the technical conditions for performing the activity (OGRM 23/07)

This Regulation establishes the (i) form and content of the Request for issuing of a Permit for processing, treatment and/or storage of waste, (ii) form and content of the permit and the technical conditions for performing the activity. The permit covers all the activities concerning treatment and processing of hazardous being excluded from the "A" and "B" Integrated Environmental Permits. This permit is intended to cover facilities dealing with treatment and processing of small quantities of hazardous waste.

2.2.7 Regulation on the form and content of the journal for waste handling, the forms and content of the forms for identification and transport of waste and content of forms for annual reports for handling waste (OGRM 7/06)

Record keeping and reporting procedures on waste management by all entities in charge at national and local level is covered by this Regulation.

The "Regulation on the format and content of the journal for records keeping on waste handling etc.", No. 07/2006 provides detailed information on the format, contents and reporting obligations in connection with waste handling. According to the rulebook, only legal entities generating more than 50 kg of hazardous waste (or more than 50 tons of non-hazardous waste) per year are obliged to maintain a waste journal and submit annual reports to the authorities on the waste handling activities.

This threshold limit for hazardous waste (i.e. 50 kg/year) implies that private GPs and small ambulatories only producing small amounts of HCW (less than 50 kg/year) do not have to maintain a waste journal or submit annual reports. However, if for instance a health centre is organising the collection and storage of HCW from a number of private GPs and small ambulatories thereby exceeding the threshold limit of 50 kg/year, the health centre will be obliged to keep and maintain a journal on the accumulated amounts of HCW on their premises.

Relevant forms in connection with HCW are the following annexes to the rulebook:

- Annex 1: Journal on records keeping (form and contents);
- Annex 2: Waste Identification Form with information on waste type and amount, transport type and planned disposal, which is to be used in connection with transport of waste from the premises of the waste generator (for hazardous waste a copy of the Identification Form shall be submitted to MEPP);
- Annex 3: Waste Transportation List, which shall serve as a consignment document following each transport of waste in order to be able to track the waste movement from the generator via the collector/transporter to the final destination of the waste at the treatment/disposal facility (for hazardous waste a copy of the Transportation List shall be submitted to MEPP);
- Annex 4: Annual report format for legal entities involved in waste handling.

Obligations are set for generators, transporters, facilities for storage, processing, treatment and disposal of wastes as follows:

- Obligation to submit records once a year
- Obligation to hold an identification form for hazardous waste
- Appropriate packaging and labelling

2.2.8 Regulation on the Manner of Handling HCW, Labelling and Forms for Handling HCW and on Types of HCW for which Processing is Prohibited

This Regulation establishes the manner of handling HCW, the manner of **labelling and record keeping** of handled HCW, as well as of all types of HCW whose processing is prohibited. The regulation has undergone several amendments due to the intensified cooperation among stakeholders (MEPP and MoH) and the joining of these authorities by the third party-the Ministry of Agriculture, Forestry and Water Economy (MAFWE), being responsible for veterinary establishments.

The Regulation provides **definitions on HCW** in the Art. 3 in the following manner, (i) Pathological, (ii) Infectious, (iii) Sharps, (iii) Pharmaceutical, (iv) Chemical, (v) Genotoxic, (vi) Containers under pressure. The Genotoxic waste was included after a round of consultations with stakeholders.

The Regulation defines the types of medical waste, how handling of medical waste shall be conducted, which includes **segregation, identification, collection, packaging, labelling, transportation, processing and disposal**.

Separation / segregation at source within the hospitals is intended to reduce health care wastes for treatment, as a result of the avoidance of its mixing with non-hazardous wastes. In the Art. 4 handling operations are listed as follows: HCW separation at source, separate collection, storage on-site, re-use, recycling, recovery, treatment, transport outside health care facilities and final disposal. In the Art. 5 separations at source, registration, labelling, packaging and record keeping are prescribed. In addition, distinction between various HCW types upon labelling and packaging by use of different colours is defined as follows:

- red colour for pathological (anatomic) waste
- yellow colour for potentially infectious waste
- green colour for pharmaceutical waste
- black or blue colour for municipal or inert waste

Apart from the colour of packaging appropriate labelling is being defined as well.

In Art. 6 preparation measures for internal transport from the generation point to the interim storage are defined. In Art. 7 recommended routes for internal transport for distinct types of wastes are given. Collection frequencies are defined In Art. 8. Recommendations concerning packaging material in order to satisfy security requirements upon the internal transport are stipulated in Art. 9. Requirements concerning safety and environmental conditions to be met on the interim storage sites are defined in Art. 10. Hygiene and safety measures to be taken by labour in contact with HCW are given in Art. 11. Outside transport is (roughly) defined in Art. 12. In the Art. 13 links to the Rulebook on the Waste handling Log book and on the waste handling annual report form (Official Gazette Nr. 7/2006) are given. In Articles 14 - 19 recommendations for treatment, recovery and final disposal (including incineration) are provided.

The obligation for generators to have a person appointed to monitor the separation at source, to collect daily quantities and store them at specially equipped area, (satisfying safety requirements for substances present at the storage area) is introduced. Also, handling measures within the hospitals (collection scheme and routes from collection points to the storage area) are to be set at the Health Care Institution level. Generators are obliged to conclude Contracts with licensed collectors of HCW.

2.3 Conceptual documents and relevant standards

2.3.1 National Waste Management Plan

The Draft National Waste Management Plan has been developed in 2005; however its adoption by the Minister of Environment is pending. A report on the health Care Waste Management has been formulated as Annex to this document. Highlighting the present situation and identifying the critical problems, this Report intends to set the scope of further activities towards an improved HCWM.

Main recommendations arising from the Annex to the NWMP can be listed as follows:

- Clarify specific responsibilities of the currently overlapping institutions: Ministry of Environment and the Ministry of Health; concerning licensing of transport companies, (the authorities are currently shared with the Ministry of Transport and Communication) additional clarifications of procedures are to be provided.
- Set up/describe an institutional framework (focusing on (i) standards, (ii) monitoring and enforcement and (iii) financing). In the NWMP this issue is given particular importance, since every single item listed above is currently suffering of inefficiency, fragmentation and lack of resource capacities.
- Investigate the potential treatment systems per type of waste; Provide an overview of each treatment system with advantages and disadvantages, capacity, investment and operational costs.
- Define standards for in-hospital activities (packaging, collection frequency, training, storage etc);
- Describe the required activities in hospitals, propose an in-hospital waste management plan;
- Estimate costs for in-hospital waste management activities (costs per bed);
- Propose a basic logistic scenario for a nation wide collection system including basic standards for storage facilities at hospitals, collection frequency, transport requirements, transfer station requirements etc;
- Propose alternatives for the basic standards, e.g. a basic scenario for storage could be a lockable room, alternatively it could be cooled, a basic scenario for transport could be transport with closed truck while alternatively it could be a closed, chilled truck etc; Investigate the incremental costs of the alternative standards;
- Investigate the costs for incineration with and without flue gas treatment system;
- Investigate if it is possible to install a uniform fee for each medical facility in the country. i.e. a hospital in Skopje has to pay the same amount per kg as a hospital in smaller towns;
- Define financing systems for hospital waste management and separate in in-hospital activities and outside-hospital activities (collection and transport to final disposal site(s));
- Propose time schedule for implementation based on discussions with relevant authorities.

Meanwhile, the Strategy on the Waste Management has been drafted and adopted by the Government. The updating of the national Plan is underway and it is expected that by the mid of 2008 they will both start the implementation.

2.3.2 Manual for handling HCW (Republic Institute for Health Protection, 2000) and trainings of hospital's staff

The awareness on the need to initiate segregation of HCW in hospitals emerged in 1999. With assistance of the WHO two series of trainings (on 16-17.12.1999 involving the General and Specialized Hospitals and on 03.02.2000 involving tertiary health care institutions) have been organized by the Republic Institute for Health Protection. Based on the training materials and experiences gathered upon trainings, a Manual on safe HCW handling has been issued in 2000 by the Republic Institute for health Protection and distributed among the health care institutions.

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2.3.3 ISO 14001 Standards

ISO 14001 is an international standard developed by the International Organization for Standardization (ISO) through dedicated technical committees representing approximately 150 countries around the world. Its purpose is to enable an organization of any type or size to develop and implement a policy committing it to prevention of pollution, compliance with legal and other requirements and continual improvement. There is an accredited Bureau for Standardization in Former Yugoslav Republic of Macedonia which may register companies that prove their commitment to apply these environmental management standards.

The realization of this commitment will be a management system that recognizes and manages the primary environmental issues through awareness and assessment of applicable legal requirements, objectives for improvement, assignment of responsibilities, competent personnel, communications, procedures, controls and monitoring, emergency response capability, self correction and assessment, and internal reviews. These processes are to be based on the Plan-Do-Check-Act cycle.

The core operating principle of health care institutions is that a clinic, which pollutes the environment, cannot at the same time provide the highest quality healthcare. This may motivate medical institutions to develop a sustainable care system to protect staff and the environment at the same time as providing quality care for patients. Moreover, hospitals have, via their vocation and activities, a greater responsibility and duty in the setting up of a sustainable development strategy.

Key programmes on implementation of ISO 14001 may include:

- An **environmentally sound purchasing policy**
- Use of **energy from renewable sources**
- Patients are served **healthy meals** made from locally-produced, often organic, ingredients.
- Health care **wastes** are sorted and recycled (such as glass, neon lights, paper and cardboard, plastic wrapping, textile, medical imaging and batteries)
- A **safe waste storage system** reduces the risk of injury and infection for both patients and staff.

In addition, hospitals may also invest in preventative care, reducing exposure to toxins and investing in public health education programmes among patients, especially new parents.

Implementation of such programmes costs approximately 10,000 EUR for 100 beds. The costs mostly come from waste sorting, collection and treatment, but these are offset by the waste reduction programme.

There are businesses in Former Yugoslav Republic of Macedonia which introduced ISO 14001 standards, however, the need to implement sound environmental management in hospitals is not broadly recognized yet.

2.4 Pending regulations

The Ministry of Environment and Physical Planning intends to harmonize the legal framework on hazardous wastes, including regulations on health care wastes. In the following table a list of pieces of legislation, which are required in order to complete the framework regulating the HCW, is given.

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Table 1 Extract from the National Plan for the Approximation to the Environmental Acquis

Title of the Draft / Changes / New	Stakeholder's responsibility	EU Measures (CELEX Nr); separated by;	Deadline (year / month) or Official Gazette	Adoption by Ministry /Government
Rulebook on minimal technical conditions for environment protection needed to be fulfilled by re-loading stations, re-loading stations locations and on deadlines for waste storing in reloading stations, according the type of waste	MEPP and MTC	31975L0442 31991L0156 31996D0350 31991L0689 31994L0031	CARDS 2004 project 2007/2	M
Rulebook on Handling Hazardous Waste	MEPP and MH	31991L0689 31994L0031	CARDS 2004 project 2007/5	M
Rulebook on minimal technical conditions to be met by incinerating installations, on type of the waste intended to be incinerated, on protecting the environment from this type of installations and on conditions for their operation	MEPP	32000L0076	2009/10	M
Rulebook on the landfill operation, monitoring and controlling in the closing phase and further care of the landfill after closing	MEPP	31999L0031 31975L0442	CARDS2004/5 projects 2007/9	M
National Waste Management Plan	MEPP		pending	M

Source: MEPP, 2006

2.5 Assessment of identified gaps

The Law on Waste Management (OGRM 68/04; 71/04) has established a legal basis for drafting sub-legislation, e.g. the regulation to cover the handling of HCW. In the Law the responsibility for drafting this legislative instrument is given to the Ministry of Environment and Physical Planning and the Ministry of Health. According to the definition of HCW in the Law on Waste Management, HCW is generated by two main sources. One generating source are medical facilities i.e. health institutions defined in the Law on Health Protection, and the other generating source are institutions for health protection of animals, i.e. veterinary ambulatories, veterinary stations, veterinary institutes, and other similar types of organisations. Obviously, the Government gave the responsibility of monitoring the handling of HCW from veterinary sources by oversight to the Ministry for Agriculture, Forestry and Water Economy or the State Veterinary Inspectorate; the latter was recently recognized by the Government as an equally important stakeholder and as a result, it was included in the process of the drafting of the HCW related secondary legislation and stated as an authority in charge if implementing them.

The Law on Waste Management establishes the institutional frames for inspection and control of the process of handling the HCW, involving only the State Inspectorate for Environment and the State Sanitary and Health Inspectorate, again excluding the State Veterinary Inspectorate. This oversight could produce many difficulties in the inspection activities regarding the HCW, because the experiences and capacities of the Veterinary Inspectorate concerning the part of HCW generated from treatment of animals is an indispensable part of conducting efficient inspection, monitoring and control of the handling of HCW.

In the Law on Communal Activities, in article 9, paragraph 1, item 14 it is stated that one of the communal infrastructural facilities are the dog-pound facilities. Taking into consideration that this type of facilities also provides medical care for dogs, these facilities produces HCW according to the definition in the Law on Waste Management. Bearing in mind that the Communal Inspectors are in charge of the mentioned facilities, their role with regard to the HCWM should be further elaborated in the Law on Waste and in the Law on Communal Activities respectively.

The Law on Waste Management in article 127, paragraph 1, item 4, prescribes that the State Environmental Inspectorate (SEI) inspects and controls whether the collection and transportation of hazardous waste is done with appropriate means and equipment specially designed and intended for the purposes of collecting and transporting hazardous waste. This provision includes supervision and control of collection and transportation of HCW as part of the hazardous waste (e.g. categories of

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hazardous waste listed in Annex 1 of the Directive on Hazardous Waste - 91/689/EEC). The provisions of the Directive on Hazardous Waste will be fully transposed when the draft Regulation on Conditions for Handling Hazardous Waste and the Manner of Packaging and Labelling the Hazardous Waste has been adopted. Although its drafting was initiated in early 2003 (PHARE funded project "Environmental Strengthening" carried out by GOPA Consultants), it has not been completed due to the lack of technical capacity of the MEPP staff in charge of legal affairs. It is assumed that additional Technical Assistance (TA) is required to guide the final effort.

The Directive on Incineration of Waste (2000/76/EC) sets the limit emission values in the process of disposal of HCW by incineration. Currently, there are no initiatives for transposing this directive into the Macedonian legislation.

The supervision of whether transports of hazardous waste (e.g. HCW) are accompanied with correct filled in consignment notes as stipulated in the "Rulebook on the format and content of the journal for records keeping on waste handling etc.", No. 07/2006 is not specifically mentioned as being the responsibility of SEI.

According to the old waste law, this responsibility was delegated to the State Communal Inspectorate (SCI) under the MoTC. Apparently there currently seems to be some uncertainty whether this should still be the responsibility of SCI or whether SEI should have this responsibility in accordance with the new waste law. The result so far is that apparently none of the two inspectorates perform systematically a supervision and inspection of HCW waste transports, including checking if necessary consignment documents are filled in and reported.

2.5.1 Gap assessment conclusions and recommendations

When drafting new amendments to the Law on Waste Management regarding the manner of handling HCW, labelling and forms for handling HCW and on types of HCW whose processing is prohibited, the Ministry on Environment and Physical Planning should take into consideration to involve additional relevant stakeholders in the inter-ministerial cooperation.

For example, taking into consideration the HCW producers in the segment of veterinary, the MEPP has to invite representatives from the Ministry for Agriculture, Forestry and Water Economy or the State Veterinary Inspectorate and Veterinarian Institute. In addition, MEPP has to invite the State Communal Inspectorate because it is a supervisory body that carries out the control of the dog-pound facilities. In respect of the current provisions of the Law on Waste Management concerning the medicals waste, it is obvious that the MEPP has given priority to the part of HCW produced in human healthcare establishments rather than the part of HCW produced in the veterinarian establishments.

Apart from the above mentioned, it is assessed that finalisation of the draft legislation on hazardous waste and specifically the rulebook on HCW will be sufficient to regulate the issue of management and treatment of HCW in the future, and in accordance with EU legislation regarding this issue, however, if it is decided that future treatment of HCW shall be based on incineration, the provisions of the directive on incineration of waste must be transposed into national legislation in the near future as well. Also, the coverage of all chains of the HCWM with clearly distinguished entity carrying out the inspection should be enabled. In other words, there should be clear division between the responsibilities of the SSI, SEI and SVI, while the Communal Inspectorate should be given the responsibility for HCW inspection at the Dog Pound facilities; however, it must be accompanied by the SEI when inspecting the collection of municipal waste being mixed with HCW in the countryside municipalities.

Another issue which has been depicted during the National Workshop (please see Chapter 5) was the need to forbid the Public enterprises to collect/transport mixed HCW; this should be integrated in the current Regulation on the Manner of Handling HCW, Labelling and Forms for Handling HCW and on Types of HCW for which Processing is prohibited.

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One important measure being part of the legislative package will be the elaboration of a detailed "Guideline on Management of HCW", which will comprise all necessary actions to be taken by individual healthcare facilities in order to comply with future HCW legislation and regulation, including which institutional strengthening measures are foreseen.

A natural starting point for preparation of the said guideline will be the Manual for Safe Management of HCW prepared by the Republic Institute for Health Protection-Skopje in 1999 and issued in 2000 (see paragraph 2.3.2), which has been distributed to all healthcare facilities in the country, and, among others, used for training of healthcare staff.

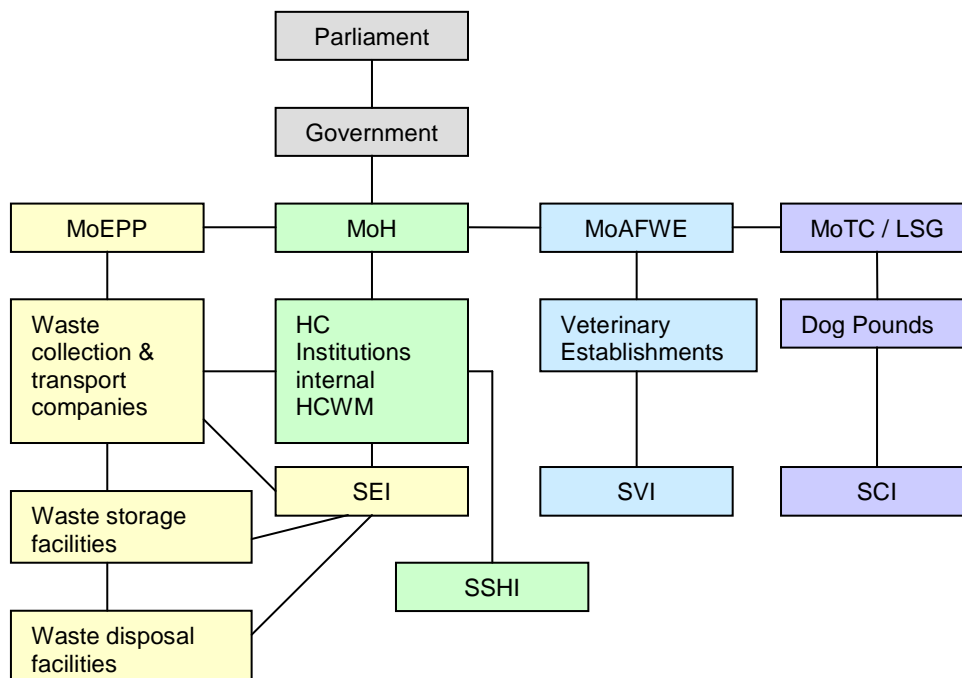
2.6 Main Stakeholders regarding HCW

2.6.1 National Authorities

Formulation of policies, drafting and law enforcement in the area of the HCWM is shared between several ministries: MEPP, MoH and MAFWE. Supervision is also conducted by a number of entities, such as the SSHI, SEI and SVI, along with the SCI for the HCW transport and handling of wastes originating from the dog-pound facilities.

In the figure below the organization of the Health Care Waste Management is given.

Figure 2 Organisation of the HCW Management in Former Yugoslav Republic of Macedonia



As it can be seen, for respective ministries are involved at certain stage of the HCWM; further, these national authorities can be divided as "environmental" and "health care" stakeholders.

Environmental area

2.6.1 Ministry of Environment and Physical Planning

With respect to HCW management, the Ministry of Environment and Physical Planning is responsible for setting emissions standards for treatment plants, approval of environmental (impact) assessments and licensing of treatment and/or disposal facilities. The supervision over the treatment and final disposal of HCW is also part of the responsibility of the Ministry of Environment and Physical Planning.

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MEPP has established an internal unit and a working group on Waste Management, which is in charge of drafting all legislative and technical instruments that implement and operationalise efficiently the Law on Waste Management. The Waste Management Unit includes one legal officer and one technical officer. The working group originally had 7 members, the legal and technical officers from the Waste Management Unit, one technical officer from the Department for Standardization, two officers from the Administration for Environment and two members from the State Environmental Inspectorate. In addition, the working group has direct consultations with MoH and draw on external expert advice from e.g. the Republic Institute for Health Protection in case of legislation concerning HCW.

Recently, MEPP has been reorganised, which has resulted in merging some of the former departments and establishing new ones. The adaptation of national law to EU Legislation is delegated to the Department for European Union, which is divided into four divisions: (i) Division on Approximation of Law and Negotiation, (ii) Division of Standards, (iii) Division of Supervision of LSG and Administrative Affairs and (iv) Division of Coordination, Monitoring and Evaluation. According to the new organisation, the unit of the Division on Approximation of Law and Negotiation, (in charge of approximation and transposition of the EU Waste related Legislation), will appoint two lawyers and one technical officer. This is likely to contribute to the finalization of pending legal documents analyzed in paragraphs 2.4 and 2.5.

However, the new working groups according to the new organisation have not been appointed yet. This gap could result in slowing down the activities regarding waste management issues, including HCW.

2.6.2 National supervision Authorities

The Law on Waste Management establishes the coordination and cooperation obligation between the SEI and the SSHI to control and inspect handling of HCW.

According to the provisions of the Law on Waste Management, the majority of the competences regarding the HCWM within the premises of HCI (segregation, internal collection and transport to the dedicated storage area) are accredited to the SSHI. On the other hand, the SEI is in charge of inspecting whether records on segregation and transport consignments are properly kept / delivered and whether the transportation, storage, as well as the treatment of HCW is done in compliance with law. The supervision and monitoring of transportation is shared with the Ministry of Transport and Communications. In addition, in the case of a treatment facility being established at the premises of a HI, the supervision of such facilities is the obligation of SEI. The inspectorates have to establish a common body to be in charge of inspections of the facilities handling HCW.

An extract of the supervision obligations of SEI (and SSHI where relevant) stated in Article 127 in the waste law and being of relevance in connection with hazardous waste handling and waste data collection are listed in the following:

- Inspect and control whether collection and transportation of hazardous waste is done with appropriate means and equipment specially designed and intended for the purposes of collection and transportation of hazardous waste (Article 27);
- Inspect and control whether hazardous waste is stored at places designated for that purpose (Article 33);
- Inspect and control whether records are kept as prescribed (Article 39 and Article 60);
- Ascertain whether consolidated annual reports are prepared and submitted (Article 39);
- Inspect and control whether hazardous waste is handled correctly (Article 57);
- Ascertain whether the obligations for issuing an Identification Form for hazardous waste have been fulfilled (Article 61);
- Inspect and control whether the hazardous waste intended for transport, storage, processing and disposal is properly packed and labelled (Article 64);

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- Ascertain whether a contract has been concluded with legal entities possessing permit for collection and transportation of hazardous waste (Article 65).

The competences of the SVI should be further included in the Law on Waste Management and subsequent regulations regarding HCW generated in the treatment and care of animals and the SCI regarding dog-pounds.

Another weakness of the present regulation (the Law on Waste and subsequent regulations) is the unclear competence concerning the inspection of the present HCW collection by the Public municipal utilities. Namely, the Communal inspectorate is in charge of inspecting these utilities, while the State Environmental Inspectorate should supervise the chain of the HCW management exiting the hospital's premises. It implies that the main gap of the present legislation is the tolerance exhibited towards the collection of mixed HCW and their unsafe disposal at local dumpsites.

2.6.3 Local Authorities

At present, only the national authorities are responsible for setting healthcare waste management policies and regulations and enforcing them. Municipal health authorities are to be involved in HCW management since the decentralization process and taking over of delegated responsibilities requires this. Furthermore, monitoring healthcare facilities, infectious diseases, and occupational health issues should follow the principle of subsidiarity, thus the municipal authorities should take it over from the national level in the future, in the scope of the next phases of the decentralization.

Municipal, and preferably in the future - inter-municipal authorities, are responsible for collection, treatment and final disposal of municipal solid waste (MSW). Since no special treatment is provided for HCW, it is handled as MSW at present. The system of transportation, treatment, and disposal of such HCW is normally considered a responsibility of the local solid waste authorities, although the Law on Waste Management does not allow this practice any longer. During the present transition period required adjustments required concerning the legal, technical, institutional and financial arrangements, that are needed in order to enforce the Law on Waste Management, will be carried out.

2.6.4 Existing HCW Treatment Company - PE "Komunalna Higiena" - Skopje

PE "Komunalna Higiena" is established and owned by the City of Skopje. The company deals with waste collection (mixed municipal waste and separate collection of HCW) in the urban area of Skopje. Among other communal services, they carry out street sweeping and maintenance of public hygiene. The company operates the Drisla Landfill (for disposal of mixed municipal waste) and the incinerator for HCW, which is installed at the premises of the mentioned landfill (regarding the incinerator see Section 6 for more details hereon). Previously, two separate companies shared these two tasks, but they were merged into one company as of 1 January 2003.

According to the Contract No. 09-8284/1 from 17.12.1999, the incinerator granted by the Department for International Development (DFID) of the British Government (Contract No. 07-5382 od 07.04.2000 with the MoH) has been delivered and an authorization issued for operation for the Sanitary Landfill "Drisla" (presently being an integrate part of the PE "Komunalna Higiena").

The reasoning behind the decision to appoint this Public Enterprise to operate the incinerator was mainly the appropriate location of the landfill, the availability of an equipped workshop, as well as the existing supply with electricity and other infrastructure. Considering this, the Ministry of Urban Planning and Construction issued general urban and architectural conditions (No. 7-7511/2 od 27.10.1999) to set and install the incinerator.

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The obligations deriving from the Contract between the MoH and the PE primarily concern the incineration fee to be paid for the service by the Health Care institutions. According to the Art 9 of this Contract, every year a new annex to the contracts should be concluded regulating the HCWM at the territory of the city of Skopje (including the incineration) among the contracting parties: PE, MoH and the Republic Institute for Health Protection (RIHP).

Presently HCW is collected from HIs (including private clinics, general practitioners, dentists, etc.) located in the urban area of Skopje. There are seven employees working for the HCW collection service, namely three drivers and three workers plus a coordinator (manager). The operation of the incinerator is carried out by a staff of five plus one manager.

HCW from the Kumanovo area is received for incineration at the landfill gate in addition to the quantities collected by the PE in Skopje. Transport of HCW from Kumanovo to the Drisla Landfill is carried out by two health care institutions. More details on HCW collection are given in section 2.8.2.

Health Care Area

2.6.5 Health care authorities

In the case of Former Yugoslav Republic of Macedonia the Ministry of Health (MoH) is the competent health authority. The responsibility of this ministry in the area of HCW management is to regulate HCW procedures inside healthcare facilities, including infection control and surveillance related to the handling of healthcare waste.

2.6.5.1 Occupational health authorities

These are the Ministry of Labour and Social Affairs and the Ministry of Health; their responsibility within HCW management is to regulate and set standards for safety of waste collectors and handling of healthcare waste, both inside and outside healthcare facilities. However, existing regulations do not relate exclusively to the handling of the HCW, but rules are mostly general. Revision, as well as harmonization, should follow.

2.6.6 Vulnerable groups in the HCWM chain

All individuals exposed to hazardous HCW are potentially at risk of being injured or infected. They include:

- **Medical staff:** doctors, nurses, sanitary staff and hospital maintenance personnel;
- **In- and out-patients** receiving treatment in health-care facilities as well as their visitors;
- **Workers in support services** linked to health-care facilities such as laundries, waste handling and transportation services;
- **Workers in waste disposal facilities**, including scavengers;
- **The general public** and more specifically the **children** playing with the items they can find in the waste outside the health-care facilities when it is directly accessible to them.

Waste management and treatment options should protect the health-care workers and the population and minimise indirect impacts from environmental exposures to HCW.

2.6.6.1 Occupational and public health risks

During handling of wastes, the medical and ancillary staff, as well as the sanitary labourers, can be injured if the waste has not been packed safely. In that respect, *sharps are considered as one of the most dangerous categories of waste*. Many injuries occur because syringe needles or other sharps have not been collected in safety boxes or because these have been overfilled. On dumpsites, scavengers during their recycling activities may also come in contact with infectious waste if it has not been properly treated or disposed of.

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The general public can be infected by HCW either directly or indirectly through several routes of contamination. Dumping HCW in open areas is a practice that can have major adverse effects on the population.

In Chapter 4 of this paper more details are given on distinct hazards originating from improper handling of HCW at hospital level and upon irregular disposal at open and uncontrolled areas.

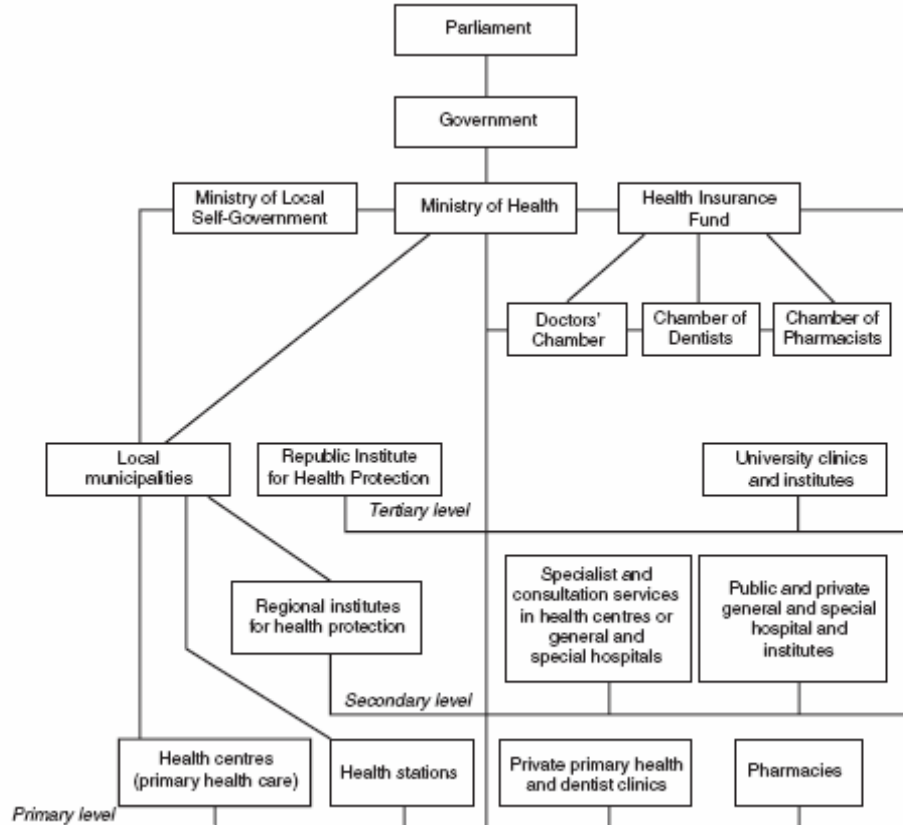
Among “recycling” practices applied in certain health care facilities particularly throughout developing countries, the reuse of syringes is certainly the most serious problem. The WHO estimates that over 20 million infections of hepatitis B, C and HIV occur yearly due to unsafe injection practices (reuse of syringes and needles in the absence of sterilization). In Former Yugoslav Republic of Macedonia such practice has been prohibited for 20 years.

2.7 National Health Care System

The Law on Health Care from August 1991, with later amendments, is the basis for the current healthcare system in Former Yugoslav Republic of Macedonia and has served as the framework for the health policy ever since. Based on this Law, the system of compulsory health insurance was established and later in 2000 supplemented by a separate Law on Health Insurance. In accordance with the mentioned laws, the organisational structure of the healthcare system comprises the Ministry of Health (MoH) and the Government in charge of health policy formulation and implementation, the Health Insurance Fund responsible for the collection and management of funds, and the HIs responsible for service delivery.

The role and capability of the Health Insurance Fund (HIF) regarding financing activities in the healthcare sector is further elaborated overleaf.

Figure 3 Organisation of the healthcare system in Former Yugoslav Republic of Macedonia



Source: RIHP, 2006

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Healthcare is delivered through a system of healthcare institutions (HIs), covering the country's territory relatively evenly, as can be observed on the map in Annex 2 comprising the major HIs in the country. The HIs range from health stations and health centres at primary healthcare (PHC) level and specialty-consultative and inpatient departments at secondary level (typically provided by public general hospitals at regional level and public and private specialised hospitals and institutes), to university clinics and institutes at tertiary level, with the latter also carrying out research and educational activities.

Recently the medical centres at municipal level have been functionally and legally divided into primary healthcare on the one hand and specialist-consultative and hospital care on the other. Moreover, some tertiary-level institutions also deliver secondary care and the system has yet to implement the necessary regulatory framework to ensure proper gate keeping and referral practices. Recent years have seen substantial growth of the private sector, especially in the field of primary health care.

Table 2 Overview of type and number of HIs in Former Yugoslav Republic of Macedonia generating HCW

<i>Type of Healthcare Institution</i>	<i>Number</i>
Tertiary healthcare level institutions comprises:	
University clinics and institutes, Skopje	5
Clinical Centre	
Dental Clinical Centre	
Clinic for Maxillofacial Surgery	
Institutes of the Medical Faculty	
Institute for Radiotherapy and Oncology	
Republic Institute for Health Protection, Skopje	1
Secondary level healthcare institutions comprises:	
Regional Institutes for Health Protection	10
Specialised Hospitals and Institutes	18
Public General Hospitals	15
Private Hospitals (incl. Military Hospital, Skopje)	4
Primary level healthcare institutions comprises:	
Health Centres	34
Health Stations	2
Other HIs comprises:	
Private healthcare for elderly people	5
Private healthcare laboratories	7
Healthcare Institutions (HIs) in total	101

Source: RIHP, Skopje

The total number of hospital beds in the country has experienced a gradual reduction during the last decade or so and is now equal to approx. 50 beds per 10,000 population. This figure is a bit less than the EU 15 average figure of approx. 58 beds per 10,000 population, but considerable higher than the WHO norm figure of 33 beds per 10,000 population.

As a result of reforms in the healthcare system initiated by the MoH a total of 2,795 health professionals working in 1,140 ambulatories located in Public Health Institutions - Health Centres have become concessionaires (i.e. job functions have been privatized) since January 2007 and have become private GPs (General Practitioners) or have started providing other specializations on a private basis (gynaecologists etc.).

In Former Yugoslav Republic of Macedonia there are in addition private 900 dentists plus 900 dentists' nurses, as well as 700 dentist concessionaires in health centres plus 700 dentists' nurses. There are 120 specialist dentists plus 120 dentists' nurses working in the public sector and the same amount in

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the private sector. In the Dental Clinical Centre-Skopje there is a total health staff of 300, of which 88 are dentists and the rest are dentists' nurses. There is a total number of 745 dentist's clinics (or ambulatories) situated outside health centres in the country. A large proportion of the dentist's clinics (approx. 32%) are located in Skopje.

There are also 117 veterinary healthcare facilities distributed throughout the country, including 40 ambulatories for pets and domestic animals and 77 animal stations.

In the context of HCW generation the above stipulated developments in the healthcare sector do not imply a dramatic change in future generated HCW amounts, but rather the contrary. Number of hospital beds is not expected to experience a dramatic change (i.e. increase in number) in the future, but instead the current use of some hospital beds could change, for instance by transferral from specialised treatment towards more common treatment requirements. However, this development could to some extent be counterweighted by the introduction of new treatment possibilities, which are not offered today in the healthcare system.

2.8 Waste Generation and handling issues

Healthcare Wastes are wastes arising from diagnosis, monitoring and preventive, curative or palliative activities in the field of veterinary and human medicine. "Very broadly HCW is defined as any solid or liquid waste that is generated in the diagnosis, treatment or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals" (BAN & HCWH, 1999). In addition, it includes the waste originating from minor or scattered sources such as that produced in the course of health care undertaken in the home (dialysis, insulin injections, etc). It is also a negligible fraction of the municipal waste, containing discarded bandages, medicines, disinfectants etc.

According to World Health Organization (WHO) approximately 85% of hospital wastes are actually non-hazardous, 10% are infectious, and around 5% are non-infectious but hazardous. In the US for example, about 15% of hospital waste are regulated as infectious waste.

In Former Yugoslav Republic of Macedonia all waste (solid or liquid) produced in Health Institutions, which originates from used objects and materials as a result of diagnosis, medical treatment and prevention of diseases in humans and animals is considered healthcare waste (HCW). The following headings are covered by the existing effective **List of types of waste** (OGRM100/04) and draft regulations (**Draft Regulation on Conditions for Handling Hazardous Waste and the Manner of Packaging and Labelling the Hazardous Waste**):

- Infectious waste
- Biological (or pathological) waste
- Sharps
- Chemicals
- Cytotoxic and cytostatic medicines
- Other medicines and pharmaceuticals
- Amalgam waste
- Radioactive waste (not in the waste list)

In this context, infectious waste is defined as all medical waste known or clinically assessed by a medical practitioner to be at risk of being contaminated with biological agents (micro-organisms, cell cultures and/or endoparasites) which have one or more of the following characteristics:

- I. likely to cause a serious human illness and to be a serious hazard for workers;
- II. capable of inducing a risk of propagation in the community (independent of the fact whether options for efficient prophylaxis or treatment exist or not);

III. are artificially cultivated to significantly elevated number,

and whose collection and disposal therefore is subject to special requirements in view of the prevention of infection spreading, like for instance HIV/AIDS, Hepatitis B and C, TBC, cholera, diphtheria etc.

In Table 3 main headings are described in more detail and also where relevant by referring to the List of types of waste (OGRM100/04), implementing the EU list of wastes (2000/532/EC) into Former Yugoslav Republic of Macedonian legislation. Waste types marked with an asterisk (*) in the waste list are considered to be hazardous waste.

Table 3 Overview of healthcare waste (HCW) types

Heading and code in waste list	Description of healthcare risk waste (HCW) types
Infectious waste 18 01 03* (human) 18 02 02* (animal)	Waste possibly containing biological agents (microorganisms, cell cultures and/or endoparasites) generated during diagnosis, monitoring, treatment, prevention or alleviations of handicaps in humans and animals, including clinic related research, e.g. petri-dishes containing live bacteria and/or vira, drain bottles containing blood and/or body fluids, bloody or humid bandage material, blood transfer systems and infusion, stoma and urine bags etc., whose collection and disposal is subject to special requirements in view of prevention of infection.
Biological (or pathological) waste 18 01 03* (human) 18 02 02* (animal)	All anatomical waste (tissue and body parts including blood and biological fluids contained herein) that are recognisable by the public or the health care workers and that demand, for ethical reasons, special disposal requirements rendering the waste non-recognisable, e.g. amputated body parts, organs, placenta, tissue samples, etc., whose collection and disposal is subject to special requirements in view of prevention of infection.
Sharps 18 01 03* (human) 18 02 02* (animal)	All medical waste with sharps or pointed objects able to cause an injury or an invasion of the skin barrier in the human body used in the care or treatment of humans or animals, e.g. syringes, needles, scalpel-blades, scissors, ampoule pieces, broken glass ware etc., whose collection and disposal is subject to special requirements in view of prevention of infection.
Chemicals 18 01 06* (human) 18 02 05* (animal)	Residue of hazardous chemicals or items containing hazardous chemicals e.g. solvents, used developer, fixer, films, used mercury bulbs, batteries, pressurized containers, etc.
Cytotoxic and cytostatic medicines 18 01 08* (human) 18 02 07* (animal)	Drugs and pharmaceuticals containing toxic substances used in cancer treatment, including materials (gloves, tissues, etc.), which have been contaminated with such toxic substances.
Other medicines and pharmaceuticals 18 01 09 (human) 18 02 08 (animal)	Spoiled or expired medicines and pharmaceuticals. Although this type of waste is not marked as hazardous in the waste list, this type of waste is typically considered as part of the HCW.
Amalgam waste 18 01 09* (human)	Amalgam waste from dental care.
Radioactive waste (not in the waste list)	Waste having a radioactivity above 0.1 Mbq per kg (or litre) must be treated and disposed of in accordance with national legislation addressing this issue, or be subject to decay by storage. Waste with radioactivity level below 0.1 Mbq per kg (or litre) is normally considered to be in-active and therefore not a radioactive waste.

Source: Rulebook on Waste Types, (OGRM100/04) implementing the EU list of wastes (2000/532/EC) into Macedonian legislation

2.8.1. HCW generation

The Former Yugoslav Republic of Macedonian Environmental Information Centre (MEIC) has so far established three cadastres comprising air emissions, waste water and solid waste. Regarding solid waste the cadastre contains approx. 600 legal entities generating solid waste. However, so far the information is limited to the waste generator type including applied technologies. **No specific waste data are so far included in the cadastre.**

According to the MEIC, which is the focal point for handling environmental data in **MEPP**, **no data on waste, being hazardous or non-hazardous, have so far been received on a regular basis.** MEIC expects that **the first annual reports from waste generators and waste treatment and disposal facilities will be received at the beginning of 2008**, because the "Rulebook on the format and content of the journal for records keeping on waste handling etc.", No. 07/2006 came into force in early 2007.

In the second National Environmental Action Plan (NEAP II) **from 2006, the amounts of hazardous medical waste (HCW) generated in the whole country are estimated to be in the range of 900-**

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1,000 tons, corresponding to 15% of the total waste generated in health care institutions. The same figures have been applied in the (still to be approved) National Waste Management Plan 2006-2012 from September 2005. In addition, it is mentioned that approx. one third of the HCW, equal to **350-360 tons/year, is collected separately in Skopje and Kumanovo and transported to the Drisla Landfill for incineration.**

Basics for estimating HCW generation can be found in many papers analyzing regional generation data based on average income of households and/or GDP. In the following table an example of such analyses is displayed.

Table 4 Total health-care waste generation by region

Region	Daily waste generation (kg/bed)
North America	7–10
Western Europe	3–6
Latin America	3
Eastern Asia:	
– high-income countries	2.5–4
– middle-income countries	1.8–2.2
Eastern Europe	1.4–2
Eastern Mediterranean	1.3–3

Source: Durand (personal communication, 1995), Johannessen (1997).

In addition, the following average percentages of various HCW types are suggested for assessing HCW in developing countries:

- 80% general health-care waste, which may be dealt with by the normal domestic and urban waste management system;
- 15% pathological and infectious waste;
- 1% sharps waste;
- 3% chemical or pharmaceutical waste;
- less than 1% special waste, such as radioactive or cytostatic waste, pressurized containers or broken thermometers and used batteries.

2.8.2 HCW Collection and transport

HCW is collected from HIs located in the urban area of Skopje using two dedicated trucks for this purpose, each equipped with 5 m³ open containers. The containers are coloured yellow and are marked with text informing that medical waste is being transported. During transport the open containers are covered with a tarpaulin to avoid spillage.

HCW from the Kumanovo area is collected by the General Hospital in Kumanovo using the Health Centre's vans; the same vehicles are used for transport to "Drisla".

The amount of HCW received at the landfill is measured at the entrance using the landfill weigh-bridge. The amount of municipal types of waste received at Drisla Landfill for disposal is approx. 500 tons/day, 7 days per week, equal to approx. 180,000 tons/year³.

For smaller HIs (typically private GPs and ambulatories) generating only small amounts of HCW, a special yellow cardboard box is used for collection and transport in Skopje. Besides the yellow colour, the box is clearly marked with the infectious symbol and text explaining that the box is for medical waste

³ Source of information: PE "Komunalna Higijena"

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only. The volume of the box is 25 litres and approx. weight when full (mostly containing sharps in the form of syringes and swabs) is 5 kg (probably more correct approx. 2-3 kg). Supply of boxes is contracted following tendering. The following picture shows the yellow box in use.



Coverage of the collection service for HCW is estimated to be close to 100% in the Skopje urban area, covering all types of HIs (hospitals, health centres, ambulatories, private GPs, etc.). For instance the number of contracts with private ambulatories has increased from 58 in 2005 to 241 in 2006⁴. The new system of privatisation by concession of the health centres will maybe be a problem, but so far the administrations of the health centres are following contract conditions on behalf of the individual private GPs.

Some of the smaller ambulatories although having a contract never or very seldomly called for collection of the yellow box, in other words the HCW was disposed by other means, probably together with municipal waste. The PE "Komunalna Higijena" has tried to solve this problem by changing the contracts so that minimum payment will be equal to two boxes collected per month.

Total amounts of HCW received at Drisla Landfill for incineration are as follows⁵:

From Skopje:

- 2005: 365 tons plus 255 boxes, in total approx. 366 tons
- 2006: 327 tons plus 1,764 boxes, in total approx. 336 tons

Although the amount coming from the larger HIs has declined, it is important to notice the sharp increase in number of yellow boxes collected.

From Kumanovo:

- 2005: 14 tons (from the Medical Centre = General Hospital + Health Centre)
- 2006: 19 tons (from General Hospital) and 3 tons (from Health Centre)

In addition to the more traditional types of HCW, the incinerator also receives **expired medicines and pharmaceuticals** from producers via the Central Bureau for destruction:

- 2005: 33 tons
- 2006: 27 tons

⁴ Source of information: PE "Komunalna Higijena"

⁵ Source of Information: PE "Komunalna Higijena"

In other towns collection of HCW is provided by Public Enterprises servicing generators of municipal waste. Consequently, the HCW is collected together with the MSW and dumped at the municipal landfills.

2.8.3 On-site HCW Treatment by HIs

Currently the only internal treatment of HCW is done in the Institutes for Health Protection as well as in Departments for Infectious Diseases located in the Clinical Centre-Skopje and in General Hospitals throughout the country.

Internal treatment is done in small autoclaves and covers only HCW such as sharps, culture plates and small glass tubes with blood samples. The treatment is typically conducted as follows:

- Sharps are collected in yellow sharps boxes and disinfected using a low level disinfectant (Isosan-G or Benzalkonium chloride or similar). When full the sharps boxes are transferred into a transparent autoclave plastic bag. In some cases when a plastic sharps box is used, this is emptied and reused due to the relatively high costs of the boxes, approx. 5 Euros per box. This is however a somewhat questionably procedure, due to risks of injury to the staff performing the emptying of the box. A sharps box should never be reused; instead, it should be disposed when full.
- Culture plates and blood tubes are collected in the same transparent autoclave plastic bag (approx. 20 litres) mounted in a rack. The bags are marked with the infectious symbol. When a bag is full it is closed using a string and transferred to an on-site autoclave (214 litre), which operates for one hour at 1.5 bar and 120 °C.

Following autoclaving the waste is without further treatment disposed into the municipal waste containers for disposal at the municipal landfill together with ordinary municipal waste.

Although the waste has been sterilised via the autoclave treatment, the sharps will still be intact and thereby pose a risk for the staff of the municipal waste collection company and scavengers at the landfill. Even the unauthorised reuse of syringes and needles could be a problem.

In the case of Skopje and Kumanovo in the current situation, this waste should be collected together with other HCW for treatment and disposal at the Drisla Landfill incinerator.

When a national HCW management system will be implemented, the use of internal autoclaves must be abolished.

2.8.4 Existing HCW Disposal Facilities

Currently the only external treatment and disposal of HCW, besides dumping at municipal landfills together with ordinary waste without pre-treatment except as stated above, is the incinerator at Drisla Landfill. Only HCW collected in Skopje (most of the quantities generated) and Kumanovo (partly) is treated in the incinerator. Recently the Faculty of Veterinary Medicine in Skopje has installed a small incinerator for animal carcasses and other animal by-products. The incinerator is yet to be put into operation, but this is expected to take place in the near future.

Although there exists an incinerator that allows for the disposal of all hospital waste generated, about 65% of the hospital wastes are deposited in open, uncontrolled municipal dumps resulting in serious health and environmental risks.

2.8.4.1 Incinerator at Drisla Landfill

The incinerator was established in 2000 based on a grant from DFID, UK. The incinerator was supplied by the British company INCINCO and is a two chamber incinerator fulfilling the British Standard BS 3316.

The main data of the incinerator are as follows:

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- Capacity: 200 kg waste per hour;
- Temperature in chamber 1: 800 °C and in chamber 2: 1,000 °C;
- No flue gas cleaning system installed.

The absence of a gas cleaning system for the delivered incinerator can be linked to the weak capacities of national stakeholders, who accepted this incomplete equipment. The Ministry of Environment was young in 2000 and was not even involved in the contracting and during commissioning. As a result, the incinerator cannot fulfil the requirements according to EU Directive 2000/76/EC on waste incineration, nor will it within reasonable costs be possible to up-grade the incinerator to do so.

Requirements according to the EU Directive 2000/76/EC are stated in the following box:

Box 1: Requirements for waste incinerators according to EU Directive 2000/76/EC
Operating conditions

TOC in slag and bottom ash < 3% or their loss on ignition value < 5% of dry matter content;
Flue gas temperature > 850 °C for at least two seconds after the last injection of combustion air. If hazardous waste with a content of more than 1% of halogenated organic substances, expressed as chlorine, are incinerated, the temperature has to be raised to 1,100 °C for at least two seconds;

Auxiliary burner installed to secure above temperature during operation, including start-up and shut-down operations;

HCW should be placed straight in the furnace, without mixing with other kinds of waste and without manual handling;

Recovery of generated heat as far as practicable.

Air emission values – daily 8 hours average according to Annex V

Total dust	< 10 mg/m ³
TOC	< 10 mg/m ³
HCl	< 10 mg/m ³
HF	< 1 mg/m ³
SO ₂	< 50 mg/m ³
NO + NO ₂ as NO ₂	< 400 mg/m ³
CO	< 50 mg/m ³
Cd + Tl	< 0.05 mg/m ³
Hg	< 0.05 mg/m ³
Other heavy metals (total)	< 0.5 mg/m ³
Dioxins and Furans:	< 0.1 ng/m ³

Measurement requirements

Continuous measurement of substances:

total dust, TOC, HCl, HF, CO and SO₂;

Continuous measurement of operation parameters: Temperature in the combustion chamber, O₂ concentration, pressure, temperature and water vapour content in exhaust gas;

At least two measurements per year of heavy metals, dioxins and furans;

Verification of residence time (two seconds) and minimum temperature (850 °C / 1,100 °C) before the plant is brought into operation.

Investment costs for an incinerator with the same capacity (200 kg/hour) and in compliance with the above stated requirements will have a budget price of approx. 1.3 Mio. Euros. In addition, operational costs due to the flue gas cleaning system and the extensive requirements for monitoring and measurements are high.

The conclusion is that **the existing incinerator cannot be used in the future if the EU Directive 2000/76/EC must be met.**

2.8.4.2 *Incinerator at the Faculty of Veterinary Medicine*

The incinerator established at the Faculty of Veterinary Medicine in Skopje is a low-capacity incinerator with two chambers (model Pyrotech A30) supplied by the British company Techtrol and fulfilling the British Standard BS 3316.

The main data of the incinerator are as follows:

- Capacity: 50 kg waste per hour;
- Minimum temperature in chamber 1: 800 °C and in chamber 2: 1,000 °C;
- No flue gas cleaning system installed.

The incinerator cannot fulfil the requirements according to the EU Directive 2000/76/EC on waste incineration stated in the box above. However, this has never been the intention, because the purpose of the incinerator is to burn animal carcasses and other animal by-products generated in the Faculty in accordance with EC Regulation 1774/2002 (previously Regulation 90/667/ECC) on health rules concerning animal by-products not intended for human consumption.

According to this regulation, Article 12, a low-capacity (i.e. less than 50 kg/hour) incinerator can be used for disposal of animal by-products, and does not have to comply with the EU Directive 2000/76/EC on incineration of waste, if the following essential requirements are met:

- The incinerator is only used for the disposal of dead pet animals and/or animal by-products of Category 2 and 3 (which in essence are animal by-products not infected with TSE/BSE);
- When located on a holding, the incinerator may only be used for disposal of material originating from that particular holding (in this case the Faculty);
- Temperature of flue gases in the incinerator shall be at least 850 °C for two seconds. Measurement of temperature shall be possible and requirements in this connection shall be stated in the approval submitted by the relevant national authority.

Based on the above it can be concluded that the **incinerator at the Faculty of Veterinary Medicine cannot be used for other types of waste, including HCW**. In this case, the incinerator would have to be able to comply in full with the requirements of EU Directive 2000/76/EC stated in the box above. In effect, this means that for instance HCW generated at the Faculty (or anywhere else) from research, diagnosis, treatment or prevention of disease involving animals as defined in the Rulebook on Waste Types, (2005) cannot be disposed in the installed incinerator at the Faculty.

2.9 Financing of the HCW Management

2.9.1 Financing of the HC System

Following independence in 1991, Former Yugoslav Republic of Macedonia set up an insurance-based health system with the Government and the Ministry of Health providing the legal framework for operation and stewardship.

The Health Insurance Fund (HIF), being responsible for the collection of contributions, allocation of funds and the supervision and contracting of healthcare providers, was established in order to support financing of the insurance-based Health Care system. **The Ministry of Finance**, with its role of setting the annual state budget, including the state funds available for the health system, is together **with the Ministry of Health sharing the chairmanship of the HIF**.

According to WHO estimates, total health expenditure as a percentage of GDP in the Republic of Former Yugoslav Republic of Macedonia amounted to 6.8% in 2002 and is therefore lower than in other ex-Yugoslav countries and the EU. The major share of HIF expenditure in 2004 (over 90%) covered

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service delivery costs, followed by pecuniary compensation of insured individuals (6.5%) and the fund's administrative costs (2.2%). **Expenditure for investment in the health sector (0.7%) continued to be insufficient.**

Since independence, the health system has struggled to deal with a 40% cut in public revenue for health services. This has resulted in funding shortages for healthcare services, pharmaceuticals and other consumables. Moreover, the supply and renewal of equipment as well as capital investment have been neglected and the HIF has accumulated substantial debts with suppliers and commercial creditors.

Based on the above it seems unlikely that major investments in a new HCW management system covering the whole country can be made based on funds from the HIF alone.

2.9.2 Financing of the HCW collection and disposal

The Government provided funds from the state budget to cover a part of the operational costs of the HCW collection and treatment system in the period 2001-2004 (MKD 6 Mio., or 98,360.00 Euros per year) and for the first six months of 2005 (MKD 3 Mio., or 49,180.00 Euros).

Current coverage of the expenditure incurred at the incineration operations at the "Drisla" Landfill is provided by a tariff levied from individual HCW generators (the HIs) based on amounts generated (per kg tariff). In other words, the polluter-pay system has been implemented in full for HIs located in Skopje.

In the contract signed between MoH, RIHP - Skopje and the operator PE "Komunalna Higijena"- Skopje (see paragraph 2.6.2) it is stated that tariffs applied for collection and treatment of HCW shall be agreed on a yearly basis between the parties. In practice this is done based on a budget calculation of annual expected operational costs prepared by PE "Komunalna Higijena"- Skopje.

Current tariffs, which have been in effect since 2003, are as follows:

- Tariff paid covering collection of HCW in the Skopje area, transport to Drisla Landfill, treatment by incineration and final disposal of slag/ashes at the landfill: MKD 56 (0.9 Euros) per kg excl. VAT (18%).
- Tariff paid for delivery of HCW at the gate at Drisla Landfill (e.g. from Kumanovo) for treatment by incineration and final disposal of slag/ashes at the landfill: MKD 45 (0.75 Euros) per kg excl. VAT (18%).
- Tariff paid for collection of yellow HCW boxes (25 litres) from private GPs and ambulatories, etc. in the Skopje area, transport to Drisla Landfill, treatment by incineration and final disposal of slag/ashes at the landfill: MKD 385 (6.4 Euros) per box excl. VAT (18%). The boxes are delivered for free by PE "Komunalna Higijena"- Skopje to the customer and the minimum payment per month per customer is equal to the tariff for two boxes, i.e. minimum payment is MKD 770 (12.6 Euros) per month excl VAT (18%). If it is assumed that the contents of a full box have a weight of approx. 3 kg, the tariff of collection, transport and treatment will be equal to approx. MKD 128 (2,1 Euros) per kg excl. VAT (18%). This tariff includes the delivery of receptacles in the form of the yellow box.
- Tariff paid for collection of yellow HCW boxes (25 litres) from private GPs and ambulatories in Kumanovo MKD 130 (2.8) per kg excl. VAT (18%), to be paid to the Kumanovo Health Centre, which is organizing collection and transport to the "Drisla" landfill.

The applied tariff level of 0.9 Euros per kg for the collection, treatment and disposal of HCW seems to be high, also compared to similar services provided in EU countries, where tariff levels for collection, treatment and disposal of bulk HCW typically range between 0.7 and 0.9 Euros per kg. This tariff includes delivery of packaging materials such as plastic bags or plastic lined cardboard boxes, which is

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not the case in Former Yugoslav Republic of Macedonia; in addition, usual tariff structures applied elsewhere should cover the necessary investments made in treatment facilities besides the operational costs.

In addition, in the case of the Health Centre – Kumanovo, which is organising the collection, transport and delivery of HCW from private GPs and ambulatories in Kumanovo, a tariff of approx. MKD 130 (2.1 Euros) per kg excl. VAT (18%) is applied for these small generators of HCW by the Health Centre, without any receptacles being delivered for free as in the case of Skopje. This tariff seems to be somewhat exorbitant compared to the tariff paid by the Health Centre when delivering the waste at Drisla (MKD 45, or 0.8 Euros per kg), even if the costs of collection and transport is taken into account. If yellow boxes for collection of HCW were delivered, the applied tariff would seem to be more acceptable.

Another example comes from the General Hospital in Stip, who has approached PE “Komunalna Higijena” – Skopje for treatment and disposal of HCW generated at the hospital. The offered tariff for this service was approx. MKD 130 per kg (more than 2 Euros per kg) excl. VAT (18%), and without collection and transport from Stip to Drisla Landfill. Taken into consideration that this hospital is a major HCW generator in the Eastern Part of the Country, where waste will be collected and transported in bulk amounts in plastic bags and by use of large containers, the offered tariff seems to be quite unreasonable, also considering that this situation is identical to the situation for the General Hospital in Kumanovo, where a tariff of MKD 45 per kg excl. VAT (18%) is applied for treatment and disposal at the Drisla Landfill incinerator.

Although the current applied tariff for HCW collection and treatment may seem high PE “Komunalna Higijena”- Skopje does not encounter difficulties in collecting the said tariff from the customers (the HIs) located in the Skopje and Kumanovo area. Apparently the HIs, although in general conceiving the tariff as high, have accepted this tariff level and are willing and can afford to pay.

Most importantly the current applied tariff is already at a level where major increases seem to be unnecessary, even if a new and nation wide HCW management system was established. This must be conceived as an extremely favourable situation.

However, current tariffs are applied for collection, treatment and disposal of HCW only in the Skopje and Kumanovo area. For HIs located outside Skopje and Kumanovo the current tariffs paid for removal of HCW collected together with ordinary, municipal waste in big containers by local public enterprises are approx. 1.0-1.2 MKD (0.016 Euros) per kg (equal to 250-300 MKD/m³, or 4.1-4.9 Euros/m³). **For HIs outside the Skopje and Kumanovo areas introduction of a special tariff for separate collection, treatment and disposal of HCW, which is approx. 50-times higher than the current experienced waste disposal tariff, will probably be regarded as quite significant. This will however also underline the necessity for the individual HI to perform a good segregation of the waste in HCW and ordinary waste in order to reduce waste disposal costs as much as possible.**

Financing of public services (including the HCW management) and the relationship between the costumers (service users) and the service providers (in most cases Public Enterprises established and owned by Government, governmental bodies and/or Local Self Government) is regulated by various set of laws (Law on Public Enterprises, law on Budgets, Law on Financing LSG etc.). Municipal waste disposal and its financing are regulated in the Law on Waste management. There isn't any specific law to cover financing of hazardous and HCW management in particular. It is considered a major gap. Also, the contract between the owner of the Incinerator (the Ministry of Health), the City of Skopje and the PE "Komunalna Higijena" is not duly implemented. This is true due to the present practice concerning the decision making on setting of the tariff in which exclusively the Council of the City of Skopje is involved. This inappropriate practice is owed to the fact that there isn't any recognized national methodology on setting of tariffs for public services, no benchmarks are set for comparison, and, more importantly, there isn't any authorized auditing entity to supervise the implementation of such methodology.

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2.10 Closing Remarks on the Present Situation

The legal framework provides for the basis to implement sound management of the HCW in the future. Gaps being created under the intensive legal drafting process towards approximation to EU legislation are recognized by responsible authorities and it is expected that pending regulations and amendments of the existing regulations will be further elaborated.

The institutional capacity to carry out policy formulation, monitoring / inspection, record keeping and reporting and enforcement of the legislation is relatively low at present. This inappropriate stakeholder capability is further aggravated by the need to share specific authorities among several institutions, which is neither clearly regulated, nor conducted in practice.

Segregation, collection and final disposal of HCW via incineration is carried out in Skopje and part of the Kumanovo area. Collection, storage, transport and incineration face various deficiencies which need to be carefully addressed and diminished in the future. This is true in particular for the absence of flue gas treatment at the "Drisla" incinerator, which causes significant risks for the human health and the environment. However, the practice in most towns in Former Yugoslav Republic of Macedonia which are not included in the system directing their HC wastes to the "Drisla" incinerator, is even worse, since previously segregated HCW is taken by municipal utilities and mixed with the MSW to be finally dumped at municipal landfills. Another questionable practice, carried out by Institutes for Health Protection, the Departments for Infectious Diseases and some General Hospitals is internal autoclaving, followed by disposal at municipal landfills, which carries the risk of accidents by staff of the waste collection company and scavengers at the landfill.

Another problem which might arise when improving the HCW Management system are present tariffs, being high for the area covered by incineration and low for HIs outside the system. In addition, transparency of setting the tariffs is not sufficient, which must be taken into account at national level via relevant regulation, either by amendments of present laws, or by issuing a new regulation (e.g. methodology on setting tariffs), as well as via authorizing an auditing and/or regulatory body.

3 NATIONAL SURVEY

A questionnaire on Healthcare Waste (HCW) Management at Healthcare Institution level was prepared by the Consultants and distributed to all HIs in the country generating HCW in January 2007. It is based on experiences gathered with the pilot survey conducted in 2004 (National Waste Management Plan) and various examples which are available throughout issued guidance notes for HCW management plans (e.g. Preparation of National Health-Care Waste Management Plans in Sub-Saharan Countries Guidance Manual supported by the Secretariat of the Basel Convention and World Health Organization). In addition, the Questionnaire on the management of wastes originating from health care establishments in selected countries of the Central and Eastern European region (BCRC Slovakia) has been used as a check list, aiming to cover all issues of importance for the assessment of the HCWM in Former Yugoslav Republic of Macedonia. The decision to deviate from the BCRC Slovakia suggested Questionnaire has been made due to its complexity and, on the other hand, the low capacity of hospital's staff to respond to demanding and detailed questions.

The questionnaire is included in Annex I and the list of HIs, which received the questionnaire, is included in Annex II.

3.1 Questionnaire Content

In the questionnaire the following issues are addressed:

- General information on the HI in question;
- Medical departments and wards;
- Segregation, types and amounts of HCW and ordinary waste;
- Types of collection equipment (receptacle) and packaging;
- Marking of collection equipment (receptacles) and use of colour coding;
- Removal/emptying frequencies for collection equipment (receptacles) applied;
- Waste storage rooms and/or areas;
- Internal handling and transportation;
- Internal treatment of waste (including costs);
- External treatment of waste (including costs);
- Wastewater treatment and disposal;
- Training of staff; and
- Organisational set-up.

3.2 Response by contacted HIs

Responses from the questionnaire survey can be summarised in the Table overleaf:

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Table 5 Questionnaire survey and responses

Healthcare Institution	No. of Q. distributed	No. of Q. returned	%
<i>Tertiary healthcare level institutions:</i>			
University clinics and institutes, Skopje	4	2	50%
Republic Institute for Health Protection, Skopje	1	1	100%
<i>Secondary level healthcare institutions:</i>			
Regional Institutes for Health Protection	10	8	80%
Specialised Hospitals and Institutes	18	9	50%
Public General Hospitals	16	8	50%
Private Hospitals	3	2	67%
<i>Primary level healthcare institutions:</i>			
Health Centres	34	10	29%
Health Stations	2	0	0%
<i>Other HIs:</i>			
Private healthcare for elderly people	5	0	0%
Private healthcare laboratories	7	1	14%
Healthcare Institutions (HIs) in total	100	41	41%

Source: National Survey 2007

Although the overall response is only 41%, it is important to notice, that response from the Clinical Centre in Skopje, accounting for approx. 19% of the total bed-capacity in the country, was obtained, together with an average response rate of 57% from the major HCW generators comprising the secondary level healthcare institutions (hospitals and institutes). In total, the responses obtained cover in-patient HIs accounting for approx. two-thirds of the total bed-capacity in the country.

3.3 Estimated HCW Quantities based on the Questionnaire

In Annex III the information on waste generation obtained from hospitals and specialised institutes (secondary and tertiary healthcare level) through the questionnaire survey is presented. It must be noted that most of hospitals (which are not part of the "Drisla" system) tried to estimate generated HCW quantities based on the volume of bags, boxes and containers and to multiply the volume with the number of monthly collection services. Specific weight of HCW was established at 130 kg/m³, and this figure was applied whenever volume was stated as generated quantity. Due to the lack of a proper segregation it was not possible to make an assessment of the composition of the healthcare waste, apart from the differentiation between the non-hazardous and hazardous components. The liquid waste, such as human blood, human blood components or products derived from blood including serum, plasma and other blood components, or bulk human body fluids could not be distinguished as a separate stream from the questionnaire. Most probably this waste component ends up in sewers without any disinfection. The estimated quantities do include all the hazardous components including this stream.

In the following, calculation and estimation of HCW amounts generated in Former Yugoslav Republic of Macedonia are made based on information and data obtained from the questionnaire survey conducted in January 2007 and also by using information from similar investigations conducted in other countries. The reason for the calculations, apart from using directly obtained data, is due to inability of HIs to report quantities for segregated HCW in absence of regular weighing. Even HIs in Skopje, which pay for the collection of HCW, were unable to state precise mass quantities. Hospitals are not inspected if they are keeping records on HCW generation, nor are they prosecuted for lack of reporting.

3.3.1 Hospitals and Specialised Institutes

The total number of hospital beds in the country (10 000) is taken as a base for calculations. Overview on the distribution of hospital beds throughout HIs is given in Annex IV.

Regarding generated HCW amounts, the figures fall into two distinctive groups; Group 1 comprising hospitals, etc. conducting “traditional” treatment and therapy, where this kind of waste is generated in bigger amounts, and Group 2, where the treatment typically only will generate small amounts, like for instance in mental hospitals, rehabilitation healthcare facilities, etc.

The calculated average values for HCW generation are as follows:

- Hospitals conducting “traditional” healthcare treatment: 0.20 kg/bed-day
(variation between 0.09 and 0.35 kg/bed-day)
- Other hospitals and specialised institutes: 0.02 kg/bed-day

Reported values from other countries, where similar investigations have been performed recently in connection with planning HCW management, are as follows:

- Estonia, variation between 0.13 - 0.47 kg/bed-day, average 0.25 kg/bed-day
- Bulgaria, average value 0.13 kg/bed-day

In Denmark, where separate collection of HCW has been conducted for several years, the reported amounts vary between 0.2 - 0.6 kg/bed-day, depending on the type of hospital.

Based on the above, an average value for HCW generation of 0.2 kg/bed-day for hospitals and specialised institutes performing secondary and tertiary healthcare services in Former Yugoslav Republic of Macedonia was used. With a total number of approx. 10,000 hospital beds in the country the current generation of HCW from this source will be: **730 tons/year**.

Total waste quantities have been further split into separate generation groups as given below.

3.3.2 Institutes for Health Protection

Institutes for Health Protection generate HCW mainly in the form of sharps, culture plates and small glass tubes with blood samples. The HCW is treated in small autoclaves (see Section 2.8.3) before disposal together with municipal waste.

In total the current generation of HCW from this source will be: **22 tons/year**.

3.3.3 Health Centres (including private GPs and concessionaire dentists)

Generated HCW amounts from health centres vary considerably according to the information obtained from the questionnaire survey, between 1.1 tons/year and up to 12 tons/year. This is probably due to improper segregation, but also to the fact that there isn't any weighing at the reception of these quantities by public utilities.

The amount of HCW delivered by the Health Centre in Kumanovo in 2006 to the incinerator at Drisla Landfill is approx. 3 tons per year. Taking into account that this is an actual measured amount and that the Health Centre in Kumanovo can be considered as an above-average size health centre, this value was used as an average value for the total of 34 health centres in the country. In total the current generation of HCW from this source will therefore be: **102 tons/year**.

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3.3.4 Dentist Ambulatories outside health centres

There are 745 dentist ambulatories situated outside health centres. No information has been obtained regarding the amount of HCW (mostly consisting of sharps and amalgam waste and other small amounts of chemical waste) generated in dentist ambulatories. It is assumed (based on analyses conducted in other countries and other published reference documents) that an average figure for generated amounts of HCW will be approx. 25-30 kg/year per dentist ambulatory. In total the current generation of HCW from this source will be: **20 tons/year**.

3.3.5 Veterinary Healthcare Facilities

There are a total of 117 veterinary healthcare facilities currently in the country, divided into 40 ambulatories for pets and domestic animals and 77 animal stations. No information has been obtained regarding the amount of HCW generated by these animal healthcare facilities. It is assumed (based on analyses conducted in other countries and other published reference documents) that an average figure for generated amounts of HCW will be approx. 0.5 tons/year for ambulatories for pets and domestic animals and 0.3 tons/year for animal stations. In total the current generation of HCW from this source will be: **43 tons/year**.

3.3.6 Pharmacies and Laboratories

There are a total of 498 pharmacies and 54 laboratories involved in healthcare activities in the country. HCW from pharmacies will only consist of a very small amount of outdated or spoiled drugs and pharmaceuticals, and HCW from laboratories will mostly consist of small test tubes and vials plus various spent laboratory agents. It is assessed that the total current generation of HCW from this source will not exceed: **10 tons/year**.

The above stated amounts can be summarised as follows:

Table 6 Current generated amounts of HCW in Former Yugoslav Republic of Macedonia, 2007

Healthcare facility	HCW amounts Tons/year	% of total
Hospitals and Specialised Institutions	730	78.7%
Institutes for Health Protection	22	2.4%
Health Centres	102	11.0%
Dentist Ambulatories outside health centres	20	2.2%
Veterinary Healthcare Facilities	43	4.6%
Pharmacies and Laboratories	10	1.1%
<i>In total</i>	927	100%

Source: National Survey 2007

The current generated amount of HCW corresponds well with the previous estimated figure of 900 - 1,000 tons/year, which was stated in already produced documents dealing with the HCW, such as the NEAP and the NWMP.

Detailed estimations on HCW generation per HI and type are presented in Annex III.

3.4 Internal Handling of HCW

Responses to the questions formulated in the Questionnaire can be found in the following ranges:

Table 7 Responses of HIs delivering back the filled in questionnaires

Handling and management issue	Yes	No
Is healthcare risk waste (HCW) separated from non-HCW (ordinary waste) at place of generation?	97.6%	2.4%
Is the generated amount of HCW reported?	0.0 %	100.0%
Is all equipment for waste collection marked or labelled clearly indicating each type of waste?	90.2%	9.8%
Are waste-specific colour codes used together with marking?	73.2%	26.8%
Have all types of waste collection equipment fixed places at ward and facility level?	100.0%	0.0%
Are the locations for waste collection equipment marked (label on the wall etc.)?	82.9%	17.1%
Are instructive posters describing how to separate the waste in use and displaced in the different wards?	56.1%	43.9%
Are special storage containers used for HCW?	87.8%	12.2%
Are there special storage rooms/facilities for HCW?	63.4%	36.6%
Are trolleys used for internal transport of HCW?	58.5%	41.5%
Is protective clothing used by sweepers and orderlies handling waste?	100.0%	0.0%
Are cleaning/disinfection of waste collection equipment conducted on regular basis?	100.0%	0.0%
Does the HI arrange waste handling training of the staff regularly?	80.5%	19.5%
Is training arranged for all new staff?	85.4%	14.6%
Has the facility established a waste management organisation?	87.8%	12.2%
Has the facility appointed a responsible person for waste management?	82.9%	17.1%
Has the facility elaborated written procedures and/or guidelines for waste handling?	92.7%	7.3%
Has the facility established an infection control organisation?	90.2%	9.8%
Has the facility appointed a responsible person for infection control?	82.9%	17.1%
Has key personnel job descriptions incorporating waste and infection control issues?	82.9%	17.1%

Source: National Survey 2007

Health staffs (doctors, nurses, laboratory technicians, dentists etc.) that are producing medical waste, separate HCW into special yellow bags and containers. 97.6% of Healthcare Institutions separate medical waste from non-HCW (ordinary/communal waste) at place of generation. **The generated amount of medical waste is not reported (100%) at a regular basis to the State Environmental Inspectorate, Ministry of Environment and Physical Planning.**

3.4.1 Staff training

The Republic Institute for Health Protection has been providing training courses for the staff employed at the Public Healthcare Institutions in 1999, 2000 and 2002. Health staff from the Public Health Institutions, as well from the State Sanitary and Health Inspectorate, the State Environmental Inspectorate and State Communal Inspectorate has been trained as well. In addition, a Manual for HCW management has been elaborated and distributed to all HIs in 2000. 80.5% of the HIs answered that they arrange waste handling training of their staff on a regular basis. In 85.4% of the cases training for proper handling of HCW has been arranged for all new staff.

3.4.2 Surveillance, control and precautionary measures

92.7% of all HIs have elaborated written procedures and/or guidelines for waste handling and 87.8% have established a waste management organization. There is a responsible person for waste management in general in 82.9% of HIs and there is an almost proper separation system in most of the HIs in Former Yugoslav Republic of Macedonia, according to the delivered Manual for HCW Management. The State Sanitary and Health Inspectorate from the MoH is responsible for supervising the yard of Health Institutions - separation, segregation, collection and internal recording of HCW management.

82.9% of the HIs have appointed a responsible person for infection control and key personnel job descriptions are incorporating waste and infection control issues. However, in most cases this person is not keeping records on generated waste, nor is he defining the most suitable routes for safe removal of HCW from the immediate generation sources.

90.2% of the HIs highlighted applying a public health approach of prevention of potential health risk and contagious diseases, paying special attention to health staff, employees from the communal sector, as well as persons that are coming into direct or indirect contact with improperly disposed solid medical waste. This is the precautionary approach for managing HCW, based upon the recommendations of the World Health Organization.

Above analyses derive from the answers from the questionnaire. After the holding of the Workshop with representatives of hospitals, it appeared that most of these statements put in the questionnaires are not correct. The real situation is described by practitioners in chapter 5 "National Workshop".

3.4.3 Packaging, labelling and internal collection of HCW

Packaging materials are from polyethylene, only in some cases bearing the symbol of biohazard. Use of polyethylene bags is prescribed in order to avoid risk of producing dioxins and furans during incineration, which would be the case if the packaging material is made of PVC. 90.2% of all equipment for waste collection is marked or labelled clearly indicating medical waste. 73.2% of the HIs use colour-coding system together with marking (use of biohazard symbol).

Generally, racks (bought or improvised) for plastic yellow bags as well as containers (for sharps, sometimes improvised from plastic bottles or canisters) are used in all HIs. When the bags are $\frac{3}{4}$ full they are closed, sealed with rope or adhesive tape, marked to which department they belong, and auxiliary staff is collecting the bags and transporting the bags to a local storage point at the ward level.

100% of HIs have fixed places at ward and facility level for collecting the HCW. 56.1% of the HIs use instructive posters (developed by WHO and RIHP) describing the procedure of separation of medical waste. 87.8% of HIs use special storage containers for HCW and 63.4% of the HIs have special storage rooms/facilities for HCW.

Minimum once per day at a scheduled time HIs transport HCW either in yellow plastic containers on wheels (70 kg) or in 58.5% of HIs on other types of trolleys, or manually to the central storage point in the yard of HI. It was reported that 100% of sweepers and orderlies use protective clothing when handling medical HCW. As a precautionary measure health and auxiliary staff use protective clothing, shoes, as well as gloves in order to prevent spreading of contagious diseases. Only two facilities reported the use of heavy boots for personal protection. Since 2005 health staff professionally exposed to HCW (during diagnostic, therapeutic and research work) is protected by vaccination against Hepatitis B.

HCW at the central storage point is stored in closed and locked facilities, non-accessible to other people, dogs and cats (this was reported in questionnaires, but upon occasional visits it was proven otherwise). In addition, in the questionnaires it was reported that cleaning/disinfection of waste collection equipment are conducted on a regular basis in 100% of the cases.

Again, it must be noted that the analyses comprises of statistics on the answers from the questionnaires, while the actual practice might differ.

3.4.4 Practical constraints on the proper handling of HCW

Although the current HCW handling practice based on the questionnaire answers seems to be rather advanced, crosschecking of answers' consistency revealed that almost all hospitals outside Skopje and Kumanovo face a wide range of practical constraints in implementing improved waste segregation, handling and storage systems, including:

- Lack of clear understanding of requirements and options among hospital managers, which is proven by the fact that it was not possible to trace generated quantities per waste streams;
- Availability of elevators to safely move waste around hospital premises;
- Problematic security of temporary storage of infectious waste within the hospitals' premises;
- Lack of adequate ventilation in storage areas located in the hospital buildings; Lack of refrigerators for low temperature storage of waste;
- Availability of appropriate bins and packaging;
- Lack of materials/equipment suppliers in Former Yugoslav Republic of Macedonia.

4 HEALTH CARE WASTE MANAGEMENT PRINCIPLES

4.1 Hazards of health-care waste

Prior to definition of concrete measure on how to create proper HCWM, hazards of the health care waste are explained in detail in the next paragraphs.

Health-care waste includes a large component of general waste and a smaller proportion of hazardous waste. This paragraph addresses the potential hazards of exposure to hazardous (or risk) health-care waste.

Exposure to hazardous health-care waste can result in disease or injury. The hazardous nature of health-care waste may be due to one or more of the following characteristics:

- it contains infectious agents;
- it is genotoxic;
- it contains toxic or hazardous chemicals or pharmaceuticals;
- it is radioactive;
- it contains sharps.

4.1.1 Hazards from infectious waste and sharps

Infectious waste may contain any of a great variety of pathogenic microorganisms. Pathogens in infectious waste may enter the human body by a number of routes:

- through a puncture, abrasion, or cut in the skin;
- through the mucous membranes;
- by inhalation;
- by ingestion.

Examples of infections that can be caused by exposure to health-care waste are listed in Table 8, together with the body fluids that are the usual vehicles of transmission. There is particular concern about infection with human immunodeficiency virus (HIV) and hepatitis viruses B and C, for which there is strong evidence of transmission via health-care waste. These viruses are generally transmitted through injuries from syringe needles contaminated by human blood.

The existence of bacteria resistant to antibiotics and chemical disinfectants in health-care establishments may also contribute to the hazards created by poorly managed health-care waste. It has been demonstrated, for example, that plasmids from laboratory strains contained in healthcare waste were transferred to indigenous bacteria via the waste disposal system. Moreover, antibiotic-resistant *Escherichia coli* have been shown to survive in an activated sludge plant, although there does not seem to be significant transfer of this organism under normal conditions of wastewater disposal and treatment.

Concentrated cultures of pathogens and contaminated sharps (particularly hypodermic needles) are probably the waste items that represent the most acute potential hazards to health. Sharps may not only cause cuts and punctures but also infect these wounds if they are contaminated with pathogens. Because of this double risk of injury and disease transmission, sharps are considered as a very hazardous waste class. The principal concerns are infections that may be transmitted by subcutaneous introduction of the causative agent, e.g. viral blood infections. Hypodermic needles constitute an important part of the sharps waste category and are particularly hazardous because they are often contaminated with patient's blood.

Table 8 Examples of infections caused by exposure to health-care wastes, causative organisms and transmission vehicles

Type of infection	Examples of causative organisms	Transmission vehicles
Gastroenteric infections	Enterobacteria, e.g. Salmonella, Shigella spp Vibrio cholerae; helminths	Faeces and/or vomit
Respiratory infections	Mycobacterium tuberculosis; measles virus; Streptococcus pneumoniae	Inhaled secretions; saliva
Ocular infection	Herpesvirus	Eye secretions
Genital infections	Neisseria gonorrhoeae; herpesvirus	Genital secretions
Skin infections	Streptococcus spp.	Pus
Anthrax	Bacillus anthracis	Skin secretions
Meningitis	Neisseria meningitidis	Cerebrospinal fluid
Acquired immunodeficiency syndrome (AIDS)	Human immunodeficiency virus (HIV)	Blood, sexual secretions
Haemorrhagic fevers	Junin, Lassa, Ebola, and Marburg viruses	All bloody products and secretions
Septicaemia	Staphylococcus spp	Blood
Bacteraemia	Coagulase-negative Staphylococcus spp.; Staphylococcus aureus; Enterobacter, Enterococcus, Klebsiella, and Streptococcus spp.	Blood
Candidaemia	Candida albicans	Blood
Viral hepatitis A	Hepatitis A virus	Faeces
Viral hepatitis B and C	Hepatitis B and C viruses	Blood and body fluids

Source: Safe management of wastes from health-care activities, World Health Organization, Geneva, 1999

4.1.2 Hazards from chemical and pharmaceutical waste

Many of the chemicals and pharmaceuticals used in health-care establishments are hazardous (e.g. toxic, genotoxic, corrosive, flammable, reactive, explosive, shock-sensitive). These substances are commonly present in small quantities in health-care waste; larger quantities may be found when unwanted or outdated chemicals and pharmaceuticals are disposed of. They may cause intoxication, either by acute or by chronic exposure, and injuries, including burns. Intoxication can result from absorption of a chemical or pharmaceutical through the skin or the mucous membranes, or from inhalation or ingestion. Injuries to the skin, the eyes, or the mucous membranes of the airways can be caused by contact with flammable, corrosive, or reactive chemicals (e.g. formaldehyde and other volatile substances). The most common injuries are burns.

Disinfectants are particularly important members of this group: they are used in large quantities and are often corrosive. It should also be noted that reactive chemicals may form highly toxic secondary compounds.

Chemical residues discharged into the sewerage system may have adverse effects on the operation of biological sewage treatment plants or toxic effects on the natural ecosystems of receiving waters. Similar problems may be caused by pharmaceutical residues, which may include antibiotics and other drugs, heavy metals such as mercury, phenols, and derivatives, and disinfectants and antiseptics.

4.1.3 Hazards from genotoxic waste

The severity of the hazards for health-care workers responsible for the handling or disposal of genotoxic waste is governed by a combination of the substance toxicity itself and the extent and duration of exposure.

Exposure to genotoxic substances in health care may also occur during the preparation of or treatment with particular drugs or chemicals. The main pathways of exposure are inhalation of dust or aerosols, absorption through the skin, ingestion of food accidentally contaminated with cytotoxic drugs, chemicals, or waste, and ingestion as a result of bad practice, such as mouth pipetting. Exposure may also occur through contact with the bodily fluids and secretions of patients undergoing chemotherapy.

The cytotoxicity of many antineoplastic drugs is cell-cycle-specific, targeted on specific intracellular processes such as DNA synthesis and mitosis. Other antineoplastics, such as alkylating agents, are not phase-specific, but cytotoxic at any point in the cell cycle. Experimental studies have shown that many antineoplastic drugs are carcinogenic and mutagenic; secondary neoplasia (occurring after the original cancer has been eradicated) is known to be associated with some forms of chemotherapy.

Many cytotoxic drugs are extremely irritant and have harmful local effects after direct contact with skin or eyes. They may also cause dizziness, nausea, headache, or dermatitis. Additional information on health hazards from cytotoxic drugs may be obtained on request from the International Agency for Research on Cancer (IARC). Special care in handling genotoxic waste is absolutely essential; any discharge of such waste into the environment could have disastrous ecological consequences.

Box 2: Cytotoxic drugs hazardous to eyes and skin

Alkylating agents

Vesicant drugs: aclarubicin, chlormethine, cisplatin, mitomycin

Irritant drugs: carmustine, cyclophosphamide, dacarbazine, ifosfamide, melphalan, streptozocin, thiotepa

Intercalating agents

Vesicant drugs: amsacrine, dactinomycin, daunorubicin, doxorubicin, epirubicin, pirarubicin, zorubicin

Irritant drugs: mitoxantrone

Vinca alkaloids and derivatives

Vesicant drugs: vinblastine, vincristine, vindesine, vinorelbine

Epipodophyllotoxins

Irritant drugs: teniposide

Radioactive waste is dealt with separately, in the next section.

4.1.4 Hazards from radioactive waste

The type of disease caused by radioactive waste is determined by the type and extent of exposure. It can range from headache, dizziness and vomiting to much more serious problems. Because radioactive waste, like certain pharmaceutical waste, is genotoxic, it may also affect genetic material. Handling of highly active sources, e.g. certain sealed sources from diagnostic instruments, may cause much more severe injuries (such as destruction of tissue, necessitating amputation of body parts) and should therefore be undertaken with the utmost care.

The hazards of low-activity waste may arise from contamination of external surfaces of containers or improper mode or duration of waste storage. Health-care workers or waste-handling or cleaning personnel exposed to this radioactivity are at risk.

4.1.5 Impacts of HC waste

While there is no scientifically documented incidence of widespread illnesses among the general public due to chemical or pharmaceutical waste from hospitals, many examples may be found of extensive intoxication caused by industrial chemical waste. Moreover, many cases of injury or intoxication result from the improper handling of chemicals or pharmaceuticals in health-care establishments. Pharmacists, anaesthetists, nursing auxiliary and maintenance personnel may be at risk of respiratory or dermal diseases caused by exposure to such substances as vapours, aerosols and liquids.

To minimize this type of occupational risk, less hazardous chemicals should be used whenever possible and protective equipment should be provided to all personnel likely to be exposed. Premises where hazardous chemicals are used should be properly ventilated and personnel at risk should be trained in preventive measures and in emergency care in case of accident.

Within health-care establishments, the surveillance of infection and record-keeping are important tools that can provide indications of inadequate hygiene practices or of contamination of the immediate environment (including contamination caused by health-care waste). Surveillance allows an outbreak of infection to be recognized and investigated and provides a basis for introducing control measures, for assessing the efficacy of those measures and of the routine preventive measures taken by the establishment and for reducing the level of avoidable infection. It will also ensure that the control measures have maximum effect and are as cost-effective as possible.

In summary, further research is necessary to increase knowledge of:

- the extent to which health-care waste is contaminated;
- the risk level for contamination of the exposed population by digestive, respiratory, and percutaneous routes;
- growth and survival of pathogens in waste during storage.

4.2 Health Care Waste Management Principles

Proper management of HCW can minimize the risks both within and outside healthcare facilities.

The first priority is to segregate wastes, preferably at the point of generation, into reusable and non-reusable, hazardous and non-hazardous components. Other important steps are the institution of a sharps management system, waste reduction, avoidance of hazardous substances whenever possible (e.g. PVC-containing products, mercury thermometers), ensuring worker safety, providing secure methods of waste collection and transportation, and installing safe treatment and disposal mechanisms.

Basic elements for the management of HCW are summarized as follows:

- Assignment of responsibilities for waste management
- Allocation of sufficient resources (financial and human)
- Waste minimization/prevention including purchasing policies and stock management practices
- Separation of waste into special HW with subcategories and HW (municipal waste)
- Implementation of safe handling, storage, transportation, treatment and disposal options
- Tracking of waste production and waste destination

An important tool for each hospital is a waste management plan, which is specific for each hospital. It addresses above topics and describes daily routines for collection, handling, separation and packaging

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of the different categories of waste. Facility managers should ensure that this plan is in place with adequate budget and personnel to implement it. In every plan an Emergency response programme should be integrated.

4.2.1 Emergency response

4.2.1.1 Principles

One person should be designated as responsible for the handling of emergencies, including coordination of actions, reporting to managers and regulators, and liaising with emergency services, and a deputy should be appointed to act in case of absence.

In health-care establishments, spillage is probably the most common type of emergency involving infectious or other hazardous material or waste.

Response procedures are essentially the same regardless of whether the spillage involves waste or material in use and should ensure that:

- the waste management plan is respected;
- contaminated areas are cleaned and, if necessary, disinfected;
- exposure of workers is limited as much as possible during the cleaning-up operation; the impact on patients, medical and other personnel, and the environment is as limited as possible.

Health-care personnel should be trained for emergency response and the necessary equipment should be at hand and readily available at all times to ensure that all required measures can be implemented safely and rapidly. Written procedures for the different types of emergencies should be drawn up. For dangerous spills, the clean-up operation should be carried out by designated personnel specially trained for the purpose.

4.2.1.2 Dealing with spillages

Spillages usually require clean-up of the contaminated area only. For spillages of infectious material, however, it is important to determine the type of infectious agent; in some cases, immediate evacuation of the area may be necessary.

In general, the more hazardous spillages occur in laboratories rather than in health-care departments.

Procedures for dealing with spillages should specify safe handling operations and appropriate protective clothing. An example of such a procedure is provided in Box 3. Appropriate equipment for collecting the waste and new containers should be available as well as means for disinfection;

In case of skin and eye contact with hazardous substances, there should be immediate decontamination. The exposed person should be removed from the area of the incident for decontamination, generally with copious amounts of water. Special attention should be paid to the eyes and any open wounds. In case of eye contact with corrosive chemicals, the eyes should be irrigated continuously with clean water for 10-30 minutes; the entire face should be washed in a basin, with the eyes being continuously opened and closed.

Box 3: Example of a general procedure for dealing with spillages

1. **Evacuate** the contaminated area.
2. **Decontaminate** the eyes and skin of exposed personnel immediately.
3. **Inform** the designated person (usually the Waste Management Officer), who should coordinate the necessary actions.
4. Determine the **nature** of the spill.
5. **Evacuate** all the people not involved in cleaning up if the spillage involves a particularly hazardous substance.
6. Provide **first aid** and medical care to injured individuals.
7. **Secure** the area to prevent exposure of additional individuals.
8. Provide adequate **protective clothing** to personnel involved in cleaning-up.
9. **Limit** the spread of the spill.
10. **Neutralize or disinfect** the spilled or contaminated material if indicated.
11. **Collect** all spilled and contaminated material. (**Sharps should never be picked up by hand**); brushes and pans or other suitable tools should be used. Spilled material and disposable contaminated items used for cleaning should be placed in the appropriate waste bags or containers.
12. **Decontaminate or disinfect** the area, wiping up with absorbent cloth. The cloth (or other absorbent material) should never be turned during this process, because this will spread the contamination. The decontamination should be carried out by working from the least to the most contaminated part, with a change of cloth at each stage. Dry cloths should be used in the case of liquid spillage; for spillages of solids, cloth impregnated with water (acidic, basic, or neutral as appropriate) should be used.
13. **Rinse** the area, and wipe dry with absorbent cloth.
14. Decontaminate or disinfect any tools that were used.
15. Remove protective clothing and decontaminate or disinfect it if necessary.
16. **Seek medical attention** if exposure to hazardous material has occurred during the operation.

4.2.1.3 Response to injury and exposure

A programme of response should be established that prescribes the actions to be taken in the event of injury or exposure to a hazardous substance. All staff who handle health-care waste should be trained to deal with injuries and exposures. The programme should include the following elements:

- immediate first-aid measures, such as cleansing of wounds and skin, and irrigation (splashing) of eyes with clean water;
- an immediate report of the incident to a designated responsible person;
- retention, if possible, of the item involved in the incident; details of its source for identification of possible infection;
- additional medical attention in an accident and emergency or occupational health department, as soon as possible;
- medical surveillance;
- blood or other tests if indicated;
- recording of the incident;
- investigation of the incident, and identification and implementation of remedial action to prevent similar incidents in the future.

In case of a needle stick injury, bleeding of the wound should be encouraged and the area should be washed under clean running water. The remaining elements of the accident response plan should then be followed.

The purpose of incident reporting should not be seen as punitive; active support by managers should encourage prompt and accurate reporting.

4.2.1.4 **Reporting accidents and incidents**

All waste management staff should be trained in emergency response and made aware of the correct procedure for prompt reporting. Accidents or incidents, including near-misses, spillages, damaged containers, inappropriate segregation and any incidents involving sharps should be reported to the Waste Management Officer (if waste is involved) or to another designated person.

The report should include details of:

- the nature of the accident or incident;
- the place and time of the accident or incident;
- the staff who were directly involved;
- any other relevant circumstances.

The cause of the accident or incident should be investigated by the Waste Management Officer (in case of waste) or other responsible officer should also take all possible action to prevent recurrence. The records of the investigation and subsequent remedial measures should be kept.

4.2.2 **Key steps during HCWM**

Generally, there are four key steps to HCW management:

1. segregation into various components, including reusable and safe storage in appropriate containers;
2. transportation to waste treatment and disposal sites
3. treatment and
4. final disposition.

The guiding principle for HW is the prevention of waste, which is accepted in general for all categories of waste in EU Member States. Prior to final disposal of waste, possibilities for reuse and recycling of waste should be investigated. Current principles of waste management are supported through paying attention to procurement of products, particular aspects like replacing certain products (such as PVC containers) by other products, because of their extended lifetime or multi-purpose use should be considered. A considerable reduction of waste can also be achieved if disposable products such as certain clothes, kitchenware, scissors, scalpels and tweezers are banned in hospitals. Thus modification of purchasing procedures at hospitals is required to further prevent the generation of waste.

Awareness and training related to a safe management of HW in hospitals should cover the following aspects:

- Awareness rising of all staff about risks related to HW
- Training of personnel regarding separation practices
- Training of waste workers regarding safe handling, storage and operation and maintenance of treatment technologies
- Display of written instructions for personnel

A clear distinction must be made between hospitals having their own treatment options and those transporting their special HW to centralized treatment facility or other hospitals.

The key to minimization and effective management of health-care waste is segregation (separation) and identification of the waste. Waste avoidance is the first step in minimising the amount of waste

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generated at a health care facility followed by segregation of the different types of waste generated at the facility.

4.2.3 Waste Avoidance and minimization

Health care facilities and the staff should take all measures possible to avoid the production of waste. Opportunities exist in:

Source Reduction:

- Purchasing reductions: careful selection of supplies that are less wasteful or less hazardous, e.g. the replacement of chlorinated solvents, where possible, with less hazardous alternatives.
- Use of physical rather than chemical cleaning methods; e.g. steam cleaning rather than using detergents and disinfectants.
- Prevention of wastage.

Management and Control Measures

- Purchase of hazardous chemicals should be centralised.
- Purchasing and use of chemicals and pharmaceuticals should be controlled and monitored on a regular basis.
- The quantities of both hazardous and general waste sent for treatment and disposal should be monitored and steps taken to minimise production as much as possible.
- Training programmes should be instituted for all staff that includes waste avoidance and minimisation of materials and wastes.

Stock management of chemicals and pharmaceuticals

- Small quantities should be ordered frequently rather than large amounts.
- The oldest batch should be used first (First in first out principal).
- All the contents of a container should be used.
- Expiry dates should be checked on delivery of supplies.
- Procedures for use of less hazardous chemicals should be investigated and applied.

In Table 9 proposals for the use of a less hazardous or a non-hazardous reagent as substitutes are displayed:

Table 9 Examples of substitution of hazardous with less hazardous chemicals

Hazardous Chemical	Safer Substitute	Used For
Acetamide	Stearic Acid	Freezing point depression
Benzene	Xylene or hexane	Many solvent uses
Benzoyl Peroxide	Lauryl Peroxide	Some polymer catalysis
Carbon Tetrachloride	Cyclohexane	Qualitative test for halides
Formaldehyde (Formalin)	Ethanol	Specimen storage
Halogenated Solvents	Non-halogenated solvents	Some extractions and other solvent uses
Sodium Dichromate	Sodium Hypochlorite	Some oxidation reactions
Sulfide ion	Hydroxide ion	Qualitative test for heavy metals
Toluene-based Scintillation Cocktail	Non-ignitable Scintillation Cocktail	Studies using radioactive materials
Chromic acid solution	Ultrasonic baths, Alconox or similar detergents, Pierce RBS-35 or similar detergents	Cleaning laboratory glassware
Mercury thermometers	Alcohol (red liquid), digital or thermocouple thermometers	Temperature
Solvents	Detergent and hot water	Parts cleaning
Oil-based paint	Latex paint	Painting operations

Source: LSUHSC Waste Minimization Program, Louisiana State University, 2005

4.2.4 Recycling

The following should be instituted:

- Recyclable products should be purchased where possible.
- Sterilisation of reusable medical and other equipment using approved sterilisation procedures should be practised.
- Under no circumstances must disposable items such as needles and syringes be recycled.

4.3 Waste Separation

Appropriate handling, treatment, and disposal of waste by type reduce costs and does much to protect public health. Segregation should always be the responsibility of the waste producer, should take place as close as possible to where the waste is generated and should be maintained in storage areas and during transport.

Segregation of health care wastes is essential for the following reasons:

- It ensures that hazardous waste and general (non-hazardous) wastes are separated. This is important in that it is dangerous to have hazardous waste being managed in the general waste stream. Conversely, the volume and contents of general waste e.g. high plastic content, is often not suitable for incineration. Secondly, from a cost point of view, it is important not to pay hazardous waste transport and disposal rates for general wastes. Segregation therefore forms the basis of a sound waste minimisation programme.
- It ensures that the hazardous wastes are sorted into correct categories for proper handling and disposal. Each type of hazardous health care waste has very specific packaging, handling, storage, transport and disposal instructions. Incorrect separation could have serious consequences e.g.

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needle stick injuries due to sharps being disposed of in infectious waste cardboard containers and sealed medium and high level radioactive sources ending up in the waste streams destined for incineration.

- From an environmental point of view, the incineration of chemicals and pharmaceuticals in infectious waste incinerators is not permitted, due to the increase in undesirable air emissions from the incinerators – in fact, the incineration of pressurised containers could lead to explosions.

Effective waste segregation is the obligation of hospital staff. The most appropriate way of identifying the categories of health-care waste is by sorting the waste into colour-coded plastic bags or containers. In addition to the colour coding of waste containers, the **following practices are recommended**:

- General health-care waste should join the stream of domestic refuse for disposal.
- Sharps should all be collected together, regardless of whether or not they are contaminated. Containers should be puncture-proof (usually made of high-density plastic) and fitted with covers. They should be rigid and impermeable so that they safely retain not only the sharps but also any residual liquids from syringes. To discourage abuse, containers should be tamper-proof (difficult to open or break) and needles and syringes should be rendered unusable. Where plastic or metal containers are unavailable or too costly, containers made of dense cardboard are recommended; these fold for ease of transport and may be supplied with a plastic lining.
- Bags and containers for infectious waste should be marked with the international infectious substance symbol.
- Highly infectious waste should, whenever possible, be sterilized immediately by autoclaving. It therefore needs to be packaged in bags that are compatible with the proposed treatment process; red bags, suitable for autoclaving, are recommended.
- Cytotoxic waste, most of which is produced in major hospital or research facilities, should be collected in strong, leak-proof containers clearly labelled “Cytotoxic wastes”.
- Small amounts of chemical or pharmaceutical waste may be collected together with infectious waste.
- Large quantities of obsolete or expired pharmaceuticals stored in hospital wards or departments should be returned to the pharmacy for disposal. Other pharmaceutical waste generated at this level, such as spilled or contaminated drugs or packaging containing drug residues should *not* be returned because of the risk of contamination.
- Large quantities of chemical waste should be packed in chemical resistant containers and sent to specialized treatment facilities (if available). The identity of the chemicals should be clearly marked on the containers: hazardous chemical wastes of different types should never be mixed.
- Waste with a high content of heavy metals (e.g. cadmium or mercury) should be collected separately.
- Aerosol containers may be collected with general health-care waste once they are completely empty, provided that the waste is not destined for incineration.
- Low-level radioactive infectious waste (e.g. swabs, syringes for diagnostic or therapeutic use) should be collected separately from other waste. The uniquely defined portion of radioactive material used in hospitals is the so-called radioactive sealed sources. Due to their limited life span, radioactive sealed sources used in radiation therapy need to be regularly removed from hospitals.

Radioactive sealed sources are kept in an inventory at the manufacturer, so they are tracked over their life span. Additionally, they should be inventoried at the hospital to guarantee that they are returned to the manufacturer and their functionality is secured. The manufacturer is responsible for the final disposal of sealed sources at suitable repositories for radioactive waste.

Separation of waste should occur as early as possible, i.e. at the time the waste is produced, for example, when an injection is given, or when packaging is removed from supplies and equipment. Hospital waste must always be separated into special HCW and other waste. It is the aim to minimize the amount of special waste requiring special treatment and disposal techniques.

Each hospital is obliged to designate a person responsible for waste management.

Since costs for safe treatment and disposal of hazardous health-care waste are typically more than 10 times higher than those for general waste, all general, i.e. non-hazardous, waste should be handled in the same manner as domestic refuse and collected in black bags. No healthcare waste other than sharps should be deposited in sharps containers, as these containers are more expensive than the bags used for other infectious waste. Measures of this sort help to minimize the costs of healthcare waste collection and treatment.

When a disposable syringe is used, for example, the packaging should be placed in the general waste bin and the used syringe in the sharps container. In most circumstances, the needle should *not* be removed from the syringe because of the risk of injury; if removal of the needle is required, special care must be taken. Appropriate containers or bag holders should be placed in all locations where particular categories of waste may be generated. Instructions on waste separation and identification should be posted at each waste collection point to remind staff of the procedures. Containers should be removed when they are three-quarters full.

Ideally, they should be made of combustible, non-halogenated plastics.

Staff should never attempt to correct errors of segregation by removing items from a bag or container after disposal or by placing one bag inside another bag of a different colour. If general and hazardous wastes are accidentally mixed, the mixture should be treated as hazardous healthcare waste.

4.4 Collection, packaging, labelling and storage

4.4.1 Collection

Nurses and other clinical staff should ensure that waste bags are tightly closed or sealed when they are about three-quarters full. Light-gauge bags can be closed by tying the neck, but heavier-gauge bags probably require a plastic sealing tag of the self-locking type. Bags should *not* be closed by stapling. Sealed sharps containers should be placed in a labelled, yellow infectious health-care waste bag before removal from the hospital ward or department. Wastes should not be allowed to accumulate at the point of production. A routine programme for their collection should be established as part of the hospital's waste management plan.

Certain recommendations should be followed by the ancillary workers in charge of waste collection:

- Waste should be collected daily (or as frequently as required) and transported to the designated central storage site.
- No bags should be removed unless they are labelled with their point of production (hospital and ward or department) and contents.
- The bags or containers should be replaced immediately with new ones of the same type.
- A supply of fresh collection bags or containers should be readily available at all locations where waste is produced.

4.4.2 Colour coding system as minimum requirements in Former Yugoslav Republic of Macedonia

Primary packaging and storage takes place where HCW is generated. Secondary packaging is used for transportation. Primary packaging of special HCW should be in leak-proof and disposable bags or containers. Initially separated sharps should be collected in puncture-proof containers. A colour code should be chosen for all special HCW.

General waste, similar to municipal waste (colour code black or grey):

Black (or grey) plastic bags, bins and containers should be used. This waste is kept and handled separately from the HCW. If at all possible, depending on the local situation, recyclables such as paper, cardboard and glass should be separated from the ordinary household waste and delivered to recycling companies.



Infectious waste (colour code yellow):

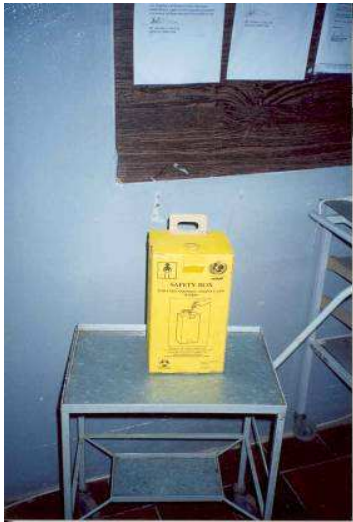
Yellow plastic bags (size 60-70 litres) should be mounted in a bag rack equipped with a lid. The thickness of plastic bag should be 0.1 mm. Plastic bags should be made of polyethylene (PE) in order to avoid potential release of dioxins and furans in case of incineration. For convenience the yellow plastic bag can be mounted in a double bag rack also holding a black (or grey) plastic bag for general waste. Also individual bag racks can be used. When full the bags are closed using a plastic string locker.

Biological (or pathological) waste (colour code red):

Cardboard box lined with a red plastic bag should be used for biological (or pathological) waste. In order to reduce costs, cardboard boxes used as packaging materials for the delivery of supplies should be reused. This waste should - due to the further treatment which is not necessarily identical to other infectious waste - be collected and stored separately in a freezer located in the central storage facility.

Sharps (colour code yellow):

Sharps should be collected in a WHO yellow cardboard box, a rigid yellow plastic box or re-used plastic cans (5-20 litres), which must be dry, equipped with a lid and clearly labelled with a yellow sticker stating "SHARPS". When full, the sharps box is transferred to the yellow plastic bag for infectious waste. Plastic boxes should be made of polyethylene in order to avoid potential release of dioxins and furans in case of incineration.



In connection with the above three types of HCW the infectious waste symbol (the Bio-Hazard Symbol) should be displayed clearly visible.



INFECTIOUS WASTE

Chemicals containing dangerous substances (colour code brown):

Puncture proof plastic or metal boxes (which can be emptied and re-used), equipped with a tight lid and clearly labelled with a brown sticker with "CHEMICAL HAZARDS" written, should be used for these chemicals. The chemicals must not be mixed in the box and should as far as possible be stored in the original packaging for easy identification of the type of chemical. The general warning symbol should be used.



CHEMICAL HAZARDS

Cytotoxic and cytostatic medicines (colour code blue):

Puncture proof plastic or metal boxes (which can be emptied and re-used), equipped with a tight lid and clearly labelled with a blue sticker with "CYTOTOXIC MEDICINE REMAINS" written, are the appropriate packaging for these substances. The cytotoxic hazard symbol should also be displayed.

Other medicines and pharmaceuticals (colour code blue):

They should be put into puncture proof plastic or metal boxes (which can be emptied and re-used), equipped with a tight lid and clearly labelled with a blue sticker with "DISCARDED MEDICINES AND PHARMACEUTICALS" written.

Amalgam waste from dental care (colour code silver):

Amalgam waste should be put into puncture proof plastic or metal boxes (which can be emptied and re-used), equipped with a tight lid and clearly labelled with a silver sticker with "AMALGAM WASTE" written. Amalgam waste should be collected separately from other chemical waste.

Radioactive waste (colour code orange):

Lead proof boxes (which can be emptied and re-used), equipped with a tight lid and clearly labelled with an orange sticker with "RADIOACTIVE WASTE" written, are the appropriate packaging for radioactive waste. The radioactive hazard symbol should be used.

**RADIOACTIVE WASTE**

Due to the very small amounts of HCW (and the general absence of biological/ pathological waste) generated at HIs other than hospitals and institutes, a more simple procedure can be established in health centres, ambulatories, private GPs, dentists, etc. In these HIs belonging to the primary health care level, a uniform type of receptacle identical to the yellow box currently being used by PE "Komunalna Higijena" in Skopje should be observed as a minimum requirement. The yellow box must then be supplemented by other types of receptacles depending on the individual type of HI and the waste they produce (e.g. boxes for drugs and pharmaceuticals, boxes for amalgam waste at dentists, etc.).

4.4.2.1 Labelling

All waste bags or containers should be labelled with basic information on their content and on the waste producer. This information may be written directly on the bag or container or on pre-printed labels, securely attached.

4.4.3 On-site Transport

Health-care waste should be transported within the hospital or other facility by means of wheeled trolleys, containers, or carts that are not used for any other purpose and meet the following specifications:

- easy to load and unload;
- no sharp edges that could damage waste bags or containers during loading and unloading;
- easy to clean.

The vehicles should be cleaned and disinfected daily with an appropriate disinfectant. All waste-bag seals should be in place and intact at the end of transportation.

4.4.4 Requirements for Storage Facilities of HCW

The storage area should have an impermeable, hard-standing floor with good drainage; it should be easy to clean and disinfect.

- There should be a water supply for cleaning purposes.
- The storage area should afford easy access for staff in charge of handling the waste.
- It should be possible to lock the store to prevent access by unauthorized persons.
- Easy access for waste-collection vehicles is essential.
- There should be protection from the sun.
- For the storage of waste for more than 24 hours, refrigeration should be provided so that the temperature does not exceed +10 degrees Celsius. The storage of biological waste might require low temperature volumes.
- The storage area should be inaccessible for animals, insects and birds.
- There should be good lighting and at least passive ventilation.
- The storage area should not be situated in the proximity of fresh food stores or food preparation areas.

A supply of cleaning equipment, protective clothing and waste bags or containers should be located conveniently close to the storage area.

4.4.5 Secondary packaging

For easy transport, the secondary packaging should consist of leak-proof solid containers mounted with wheels. The colour code should comply with primary packaging. In Germany, for example, anatomic HW should only be transported in burnable one-way containers. In any case, an unauthorized opening of containers carrying special HCW should be prohibited at all times.

4.4.6 Transportation vehicles and containers

Waste bags may be placed directly into the transportation vehicle, but it is safer to place them in further containers (e.g. cardboard boxes or wheeled, rigid, lidded plastic or galvanized bins). This has the advantage of reducing the handling of filled waste bags but results in higher disposal costs. These secondary containers should be placed close to the waste source.

Any vehicle used to transport health-care waste should fulfil the following design criteria:

- The body of the vehicle should be of a suitable size commensurate with the design of the vehicle, with an internal body height of at least 2.2 meters.
- There should be a bulkhead between the driver's cabin and the vehicle body, which is designed to retain the load if the vehicle is involved in a collision.
- There should be a suitable system for securing the load during transport.
- Empty plastic bags, suitable protective clothing, cleaning equipment, tools and disinfectant, together with special kits for dealing with liquid spills, should be carried in a separate compartment in the vehicle.
- The internal finish of the vehicle should allow it to be steam-cleaned, and the internal angles should be rounded.
- The vehicle should be marked with the name and address of the waste carrier.
- Vehicles or containers used for the transportation of health-care waste should not be used for the transportation of any other material. They should be kept locked at all times, except when loading and unloading. Where the use of a dedicated vehicle cannot be justified, a bulk container that can be lifted on to a vehicle chassis may be considered. The container may be used for storage at the health-care establishment and replaced with an empty one when collected.

The same safety measures should apply to the collection of hazardous health-care waste from scattered small sources.

Health-care establishments that practice minimal programmes of health-care waste management should either avoid off-site transportation of hazardous waste or at least use closed vehicles to avoid spillage. The internal surfaces of any vehicle used for this purpose should be easy to clean.

4.5 Handling of HCW contained in the municipal waste

Advances in medicine now allow us to monitor and treat some elements of our health and the health of our family at home. These advances can save us costly and frequent visits to health care professionals for such health monitoring and treatment as blood glucose, common colds and some allergic reactions, and kidney functions/dialysis.

An increasing challenge that comes with these medical advances is the proper management of the waste generated. These wastes include:

- Used needles, syringes, and lancets
- Medicine - unused or outdated
- Broken thermometers
- Contaminated dressings/Dialysis filter material

While used needles, syringes, lancets and other sharp implements may be safely disposed with the other solid wastes from the home, it is important to exercise care in packaging needles, syringes, and lancets for disposal. The safe packaging of these wastes may be accomplished very simply at home. Use a rigid plastic bottle with a tight fitting cap, such as empty laundry detergent or fabric softeners bottles to store and dispose "sharps." Do not put sharp objects in any container that will be recycled or returned to a store. Needles and syringes need not be recapped. The rigid bottle will minimize the potential for needle sticks. When the bottle is full, add plaster of Paris to the level of the neck of the container, cap it tightly, and place it with your other solid waste for disposal.

Unused and outdated medicines stored at home provide a considerable risk to children as well as individuals with vision or mental impairment. These medicines may be safely disposed by emptying the medicine into the toilet and flushing. Be certain all of the medicine goes down the drain. Thoroughly rinse the medicine container with warm water. Cap the empty container tightly and dispose with other solid waste from the home. Do not give the empty container to a child as a toy. Children should not associate medicine with play or candy.

Mercury filled thermometers provide an effective low cost method for monitoring body temperature. A broken thermometer presents two immediate challenges, the broken glass and the metallic mercury. Both of these materials should be scooped immediately into a rigid container with a tight fitting cap and carefully sealed. Special care must be taken to ensure that all of the mercury "beads" are contained. Many of them may be very small and they will scatter on impact. The contained mercury and glass should be sent to an appropriate recycle operation. Laboratories, fluorescent light recyclers and your state or local recycle coordinator should be able to help you find a recycler. Care should also be taken to avoid contact of the mercury with any items made of gold. Should a gold-to-mercury contact occur, contact a jeweller or chemist immediately to have the gold treated for mercury removal. This treatment should not be attempted at home.

4.6 Transportation of HCW on public roads

Health-care waste should be transported by the quickest possible route, which should be planned before the journey begins. After departure from the waste production point, every effort should be made to avoid further handling. If handling cannot be avoided, it should be pre-arranged and take place in adequately designed and authorized premises. Handling requirements can be specified in the contract established between the waste producer and the carrier.

Transportation of special HW needs to be controlled meaning that it should be ensured that the waste arrives at its destination. This can be achieved by a consignment note to be signed by the recipient of waste and returned to the hospital. Control of the waste stream is in particular important, if an unintended recycling of items such as used syringes occurs, because they are considered as valuable objects.

4.7 Treatment technologies for hospital waste

4.7.1 Environmental Concerns

Currently, each technology that ensures destruction or elimination of infectious and other types of special HCW potentially produces a secondary waste stream. When choosing an appropriate technology (e.g., incineration, autoclave, or microwave irradiation) for the type of HCW, a manager must review the secondary waste stream and the affected population. Weighing the balance of the technology (and its secondary waste stream) with the current problem (while assessing the cost benefit and available technologies) is a key point in decision-making. Quite often, successful HCW management includes several technologies within one facility.

Creation of dioxins (dibenzo-p-dioxins) is of particular concern due to the possible carcinogenic nature of these compounds. Incineration can create dioxins, depending on the HCW material and the temperature (and scrubbers) of the incinerator plant. Plastics and chlorinated substances (such as dyes) can create dioxins when incinerated. Therefore, segregation of materials is vitally important. Furthermore, ensuring that the incinerator plant continually burns its materials at a temperature at or above 1,200 degrees will virtually eliminate dioxins from release. Incineration remains an important technological tool in HCW management due to its ability to completely destroy infectious or contaminated materials (such as used syringes). In fact, in some instances, the public health threat from contaminated needles is of a much greater concern and probability than that of potential dioxins. Decision makers must make the difficult choice for the greater good of the population in a particular time and place.

4.7.2 Comparison of available HCW treatment options

Decisions regarding treatment technology should be made at hospital level; however responsible personnel for waste management in the hospital should be in close contact with the competent authority. In principal there are three parties involved in waste management, the producer of the waste, the transporting/disposal party and the competent authority. It has been the experience in many EU Member States that cooperation between these three parties is a good approach to solving problems regarding waste management. Additionally, it also serves to engage the general public as early as possible, which should be considered as an additional party when it comes to siting of new Health Care Waste incinerators.

Treatment and disposal of HCW generally aim at:

- destruction of viable infectious organisms
- destruction/transformation into harmless forms of waste, used pharmaceuticals and medicines
- destruction of sharps and other materials capable of causing physical injuries
- final disposal / destruction of body parts, tissues, blood and other organic material
- avoidance or minimization of secondary impacts from the disposal system

The largest portion of HCW is regular municipal waste that might be subject to treatment and disposal, which is not specific to waste from hospitals. Thus, the first step in treatment and disposal is to ensure that all regular waste is safely sent to the normal municipal waste management system. The remaining fraction of special HCW amounts to about 10-15%.

Unfortunately, in Former Yugoslav Republic of Macedonia even municipal wastes are not managed in an environmentally safe manner.

Broad comparisons of various treatment options based on general international experience are summarized in the following table.

Table 10 Comparison on HCW disposal options

	Open burning	Municipal dumps	On-site incineration	High temp. incineration	Autoclaving	Microwaving	Chem. sterilization	Sanitary landfill
infectious organisms	poor	none	poor to moderate	very good	good	good	good	good
body parts, blood, etc.	good	none	good	very good	poor to moderate	poor to moderate	poor to moderate	good
pharmaceuticals	good	none	good	very good	none	none	poor to moderate	moderate to good
sharps	moderate	none	moderate	very good	poor to moderate	poor to moderate	moderate	moderate

Source: Safe management of wastes from health-care activities, WHO 2004

4.7.3 Landfilling

Landfilling of special HCW together with other municipal waste should only be considered for small selected quantities of waste. This practice is still carried out, in particular in rural areas. In larger cities with several hospitals it is rather recommended to use a special landfill cell. The cell should be fenced to restrict access and the deposited special HCW should be treated with lime. A thin soil cover should be placed on top of each load. However, the current trend leads towards a ban of land filling of special HCW without applying a treatment technology prior to disposal. This circumstance is documented through EU Directive EC/99/31. The direct land filling of special HCW should be phased out in Former Yugoslav Republic of Macedonia as alternative waste treatment technologies (autoclave, microwave and incineration) are established.

Since it cannot be ruled out completely that sharps are not disposed of at a controlled landfill, it is advisable to encapsulate sharps in case the final destination is unclear. However, the ultimate goal is to ensure that special HCW should never be disposed of in open dumps in order to avoid the risk of infections. This public risk applies in particular to children that can come in contact with infectious wastes from hospitals. The purpose of encapsulation is to isolate these dangerous items from humans and the environment. Encapsulation involves filling containers with sharps and in some cases with other special HW, adding an immobilizing material, and sealing the container. Cubic boxes made of high-density polyethylene or metallic drums are used as containers. Plastic foam, bituminous sand, cements mortar or clay material are used as immobilizing material. The main advantage of encapsulation is that it is very effective in reducing the risk of scavengers gaining access to the special HCW.

4.7.4 Incineration

Incineration used to be the method of choice for most special HCW and is still widely used. However, recently developed alternative treatment methods are becoming increasingly popular such as autoclave and microwave treatment. Furthermore, in spite of the existence of a hospital waste incinerator in Former Yugoslav Republic of Macedonia, about 65% of the hospital wastes are deposited in open, uncontrolled municipal dumps resulting in serious health and environmental risks.

A very common way of treatment of HCW has for a long period been incineration. At the high temperatures in an appropriate incinerator, the micro-organisms are rendered harmless and the residues from the incineration can be disposed of at a landfill. Depending on the character of the

residue - hazardous or non-hazardous - the residue must be disposed of at the appropriate type of landfill. Normally the residues should be considered hazardous.

Process flow:

An incinerator facility for HCW will normally include a cold storage room for reception of waste and in addition flue gas cleaning equipment and storage for ash and slag and flue gas cleaning products. There are various types of waste incinerators. The combustion chamber can be rotating or fixed. Several designs and brands are on the market.

Most incinerators have a primary and a secondary combustion chamber. The waste is loaded into the primary chamber and ignited. It operates typically at temperatures of around 800 -1,000°C and the waste is kept there until all waste has been turned into ash.

Smoke and gaseous products from the combustion pass into the secondary chamber, which acts as an afterburner, where the gases and smoke are oxidized at temperatures around 1,100 °C.

Acid gases, such as hydrogen chloride and sulphur dioxide are main potential pollutants from incineration and also heavy metals vaporised from the waste at the high temperatures may be present. Furthermore, any combustion process has the potential to produce halogenated dioxins and furans. The content of chlorine, e.g. in the form of PVC plastic products, enhances the formation of these compounds in the incineration process.

In general, the flue gas is first cooled from above 1,000 °C to around 120-140 °C by passing it through a boiler. This produces hot water or steam, which can be used to generate electricity and in the heating system of the treatment facility. The lowering of the flue gas temperature prevents that dioxins can be reformed, and also the subsequent treatment of the gasses with e.g. lime is more efficient at lower temperatures.

Dioxins can be formed at temperatures between 250 °C and 450 °C. At temperatures above 1,000 °C they are destroyed and below 250 °C they do not form. This means that dioxins are destroyed in the secondary combustion chamber and the quick cooling prevents reformation. Small remains of dioxins that pass through the incineration and cooling can be removed from the flue gas by activated carbon.

Neutralisation and absorption of organic pollutants, especially dioxins and furans, in the flue gas takes place in a reactor, where e.g. lime and activated carbon are injected into the flue gas. The lime neutralises the acid gases and the carbon removes dioxins and furans together with the other organic substances and heavy metals, e.g. mercury and cadmium, by absorbing the substances onto its surface.

Filter bags remove the reaction products from the reaction between the flue gases and the lime together with activated carbon from the flue gas and particles from the incineration process are filtered out.

The spent lime and the carbon, also called the flue gas cleaning product, must be disposed of at a landfill, in general a landfill approved for hazardous waste, as the flue gas cleaning product often has to be classified as hazardous waste according to the legislation.

After passing the reactor and the filter bags, the flue gas is discharged to the atmosphere. The levels of harmful pollutants and dust must be measured - some of the parameters on a continuous basis – and must comply with EU Directive 2000/76/EC.

Ash and slag must be removed from the combustion chamber. This can be done either automatically or manually. The ash and slag must be disposed of at a landfill. If the ash and slag are classified as hazardous waste, the disposal must take place at a landfill dedicated for hazardous waste.

Waste types that can be incinerated:

Nearly all types of hazardous waste from HIs can be incinerated in modern incinerators. However, depending on the flue gas cleaning system, some substances are not suitable for incineration and should be disposed of in other ways.

Incinerators can destroy infectious waste, rendering biological and infective waste harmless, as well as most chemicals. Incineration can be considered as an all round treatment option. However, mercury containing waste (e.g. amalgam waste from dentists) should not be incinerated. The same applies to radioactive waste and waste containing significant amounts of heavy metals.

Emissions from incineration:

The emissions from incinerators are regulated by the legislation. In order to reduce the emission of hazardous substances, extensive flue gas cleaning is required. Nevertheless, a certain emission of hazardous substances takes place during operation. It should be noticed that the EU regulation, currently formulated in EU Directive 2000/76/EC on incineration of waste, has for many years steadily introduced more stringent emission limits and that this development obviously will continue.

The establishment of an incinerator for treatment of medical waste would require the transposition of the provisions of the EU Incineration Directive into Former Yugoslav Republic of Macedonia legislation.

Costs for incineration:

Direct plant investment costs for an incinerator having a capacity 250 kg/hour equal to 1,200 tons/year (operated in two shifts (16 hours) per day, 300 days per year) and in compliance with the EU Directive 2000/76/EC will have a budget price of approx. 1.5 Mio. Euros. In addition, direct plant operational costs due to the flue gas cleaning system and the extensive requirements for monitoring and measurements are high. The direct plant related operational costs (fuel oil, electricity, chemicals for flue gas cleaning, etc.) can be estimated to approx. 200-250 Euros per ton of waste treated.

Benefits and drawbacks of incineration:

The benefits of controlled incineration include the volume reduction of the waste and the removal of pathogenic risk. Drawbacks to incineration include the potential for large capital and operating expenses, the need for skilled labour to operate and maintain the system and the potential for toxic emissions to the air in case no emission control equipment is installed.

Proper incineration is the high technological approach that can adequately treat all types of special HCW and is the preferred option for cytotoxins and other pharmaceuticals. It is important that combustion takes place at a sufficiently high temperature ranging between 1,000°C and 1,200°C for a long enough time. Also, the combustion chamber should allow for sufficient turbulence and oxygen for a complete combustion to be achieved and problematic gases to be minimized. These large modern treatment facilities are, of course, not an option for single hospitals, but for a centralized solution. In any case, the incineration of special HW generates air emissions and ash. Consequently, disposal at landfills is not completely prevented and existing air emissions limits must be observed, such as the EU Directive EC/2000/76 on the incineration of waste.

In addition, treatment facilities of medical waste based on incineration are obliged to obtain an A integrated environmental permit based on an Environmental Impact Assessment (EIA) in accordance with the Law on the Environment.

Incineration of PVC has the potential to generate emissions of dioxins. The use of PVC as a packaging material in hospitals and other health care establishments should therefore be phased out and eliminated in those areas where incineration facilities are being utilized for waste treatment.

Small capacity incinerators are in use in Former Yugoslav Republic of Macedonia at single hospitals (military hospital in Skopje, Central Hospital in Skopje, etc.), but because of their simple technology,

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they constitute in general a serious air pollution hazard to the surrounding area. All workers involved in the operation of such small-scale incinerators should have available protective equipment, such as gloves, boots and aprons.

The World Health Organization (WHO) has recommended the closure of small incinerators world-wide that are not operating satisfactorily.

4.7.5 Autoclaving

Autoclaving is the exposure of waste to heat in form of steam in order to obtain deactivation and possible sterilisation of the waste. In an autoclave, the infectious waste is heated with steam under pressure (at least 2 bars and 121°C). The process takes place in a tank. Several types of autoclaves have been developed. Some are equipped with a rotating cutter inside the tank, securing that the waste is shredded and thereby properly exposed to the steam, making the process more efficient and at the same time reducing the volume of the waste.

In some autoclaves the sterilisation process takes place using saturated steam building up a pressure of more than 3 bars and a temperature of approximately 135 °C. A system of rotating cutting blades inside the autoclave cuts plastic bags and cans holding the waste, thereby ensuring all waste to be exposed to the steam under pressure. The sterilisation cycle typically will last approximately 45-60 minutes, including heating up and cooling down periods.

Autoclaves with cutting and rotating systems inside the tank should be preferred. Cutting and shredding ensures efficient sterilisation, as the steam can penetrate the waste more easily when it is divided into small particles and as cold spots are avoided. Thereby the treatment time can be reduced as well. If the waste is shredded outside the autoclave prior to autoclaving, the shredder must be disinfected on a regular basis. This work can cause health and safety problems, also in connection with the maintenance of the shredder. Autoclave systems both with and without cutter/shredder built-in, are also often equipped with a secondary stage shredder, that further shreds the autoclaved (and sterile) waste.

Waste types that can be autoclaved:

It can be assessed that about 90-95 per cent of the yearly amount of HCW in a given area can be treated in appropriate autoclaves. Chemicals, expired or unused drugs and pharmaceuticals including cytotoxic waste and mercury containing waste must be collected separately and sent for treatment elsewhere in dedicated facilities (e.g. at a national centre for treatment of the much larger amounts of hazardous waste generated by industry and households). Also the biological (pathological) waste, depending on the chosen autoclave, could be treated more appropriately by incineration or by burial at cemeteries, e.g. because of ethical considerations.

Residues from autoclaving:

The residue from autoclaving in a dedicated HCW autoclave will in principle contain the same substances as were fed into the autoclave. However, due to the shredding process, a considerable volume reduction will take place, approx. up to 80%. Also some limited reduction of weight will take place due to evaporation of water from the waste. The treated waste is unrecognisable.

No other waste than the HCW being treated in the facility will be produced. The HCW will after treatment be sterile and unrecognisable (a shredder is normally standard in autoclaves), and can be disposed of at a landfill together with ordinary municipal waste in compliance with the EU Landfill Directive.

Emissions from autoclaving:

There will be emissions from evacuation of the autoclave vessel before and after each sterilization cycle. Active carbon filters are normally applied for odour elimination and in addition the air evacuated

before the sterilization cycle will be exposed to a steam treatment before being emitted to the surroundings.

An autoclave will produce a minor amount of wastewater in the form of condensed steam when the autoclave is evacuated following the sterilisation cycle. The wastewater is sterile and the pollution strength will be similar to or less than ordinary household wastewater. Most of the steam used for disinfection can be condensed after use and the water recycled.

Establishment of an autoclave for treatment of medical waste would need to obtain the less stringent B integrated environmental permit based on an environmental screening in accordance with the Law on the Environment.

Costs for autoclaving:

Direct plant investment costs (budget prices) for autoclaves including shredder and other auxiliary equipment (e.g. steam generator if steam is not available on site, cooling tower, air compressor, etc.) having the following capacities (annual capacities based on two shifts (16 hours) per day, 300 days per year) are:

- 75 kg/h (equal to 360 tons/year):	Euro 300,000
- 125 kg/h (equal to 600 tons/year):	Euro 500,000
- 210 kg/h (equal to 1,000 tons/year):	Euro 600,000
- 350 kg/h (equal to 1,600 tons/year):	Euro 700,000

Direct plant related operational costs (steam production, electricity, etc.) can be estimated to approx. 100-150 Euros per ton of waste treated.

4.8 Training and campaigns

To be effective, a HCWM policy has to be applied carefully, consistently and universally. Training is a crucial aspect to successfully upgrade HCWM practices. The overall aim of training is to develop awareness of the health, safety, and environmental issues relating to HCWM. It should highlight the roles and responsibilities of each actor involved in the management process of the HCW (duty of care).

Previous trainings conducted in Former Yugoslav Republic of Macedonia were focused upon the technical level - Main nurses, who are predominantly involved in the HCW segregation at the place of generation. Although the National Survey (2007) indicated the existence of appointed managers being responsible for planning of the HCWM at hospital level, developing written procedures and monitoring the daily activities, it is certain that even if there is a manager appointed, the practice is not documented with any policy in a written form.

Apart from the chosen target group, the most of already designated trainings in Former Yugoslav Republic of Macedonia have dealt with the HCW segregation practices. The latest training cycle being financed by Defra (Department for environment, food and rural affairs) included also the exercises on waste identification, record keeping, as well as filling in transport forms. None have been focused on the designing of the internal hospital policy, nor have they made any distinction between the technical instructions intended specifically for different hierarchy HCWM levels, including monitoring and inspection.

Separate but equally important training programs should be designed for the following categories of personnel: 1) hospital managers and administrative staff responsible for implementing regulations on HCWM, 2) medical doctors; nurses and assistant nurses, 3) cleaners, porters, ancillary staff, and waste handlers, 4) municipal solid waste laborers and waste pickers.

Staff education programmes should cover:

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- Information on, and justification for, all aspects of the HCWM policy;
- Information on the role and responsibilities of each hospital staff member in implementing the policy;
- Technical instructions, relevant for the target group, on the application of waste management practices; Information on monitoring techniques.

The overall approach to capacity building must complement the introduction of new equipment and ensure that issues that had been shown to evoke strong feeling were addressed. Thus general assistants should be supplied with new protective gloves and sharps containers were conveniently sited in areas of high activity. Training should therefore be an integrated component of a broader strategy. The capacity building programme should involve:

1. Provision of new policy and procedures for HCW Management written as a Code of Practice
2. Introduction of improved monitoring and reporting
3. The introduction of a dedicated Health Care Waste Manager and an Assistant
4. Knowledge, attitudes and skills training
5. Awareness activities
6. On the job skills coaching
7. Evaluation of capacity building activities

The target group for the most needed training cycle are the three inspectorates: the State Environmental Inspectorate, State Sanitary Inspectorate and the State Veterinary Inspectorate.

In addition, trainings should be organized for the following players in the HCWM:

- licensed transport companies for hazardous waste
- operators of treatment/disposal facilities

More information on the method to be chosen upon the developing the training curricula is given in the Chapter 7 "Conclusions and recommendations".

5. NATIONAL HEALTH CARE WASTE STRATEGY

5.1 Forecast on HCW generation

In order to determine whether a dramatic change in the generation of HCW will take place for instance during the coming 10-year period, a number of factors, which could have an influence hereon, must be assessed.

Some of the more important factors are the following:

- Population growth;
- Economic and healthcare development;
- HCW management development.

The current population growth rate is very low, only approx. 0.2%. There is no reason to expect a dramatic change in the population growth rate during the coming 10-year period and therefore no significant influence on HCW generation is expected due to change of population size.

The current growth rate for GDP is approx. 3.2% and a considerable higher growth rate must be assumed before more funds will be allocated to the healthcare sector. Taking into account the current state-of-affair of the HIF (see Section 2.9.1) it is unlikely that a dramatic change in funding of activities in the health sector will take place in the short-term. Also, there are no plans for increasing the number of hospital beds, rather the contrary. **As hospitals are the main generator of HCW (approx. 79%) and the number of hospital beds will be more or less status-quo, the change in HCW generation will be limited or none.**

Probably the greatest influence on HCW generation will arise from future improvements of the HCW management itself. Improvements hereto will unquestionably be made if a national strategy on HCW management is adopted together with the necessary legislative enforcement.

Based on the above it is assessed that in order for a future national system for handling and treatment of HCW to have a sufficient capacity during the coming 10-year period, the design capacity should be 30% above the current generated amount of HCW. The design capacity of the HCW treatment system should therefore be approx. 1,200 tons/year.

5.2 Selected development scenarios for treatment of HCW

The prognosis of the HCW generation in combination with the collection / transport and treatment options have been analysed in light of the (i) distribution of generating sources throughout the country, (ii) the amount / composition of the HCW for disposal and the (iii) advantages / disadvantages of the centralized versus decentralized systems and the treatment technologies.

The following three development scenarios for treatment of HCW have been selected for further investigation in the present HCW Strategy:

- Scenario 1: Central treatment in one incinerator located in or nearby Skopje;
- Scenario 2: Central treatment in one autoclave located in Skopje;
- Scenario 3: Decentralised treatment in three autoclaves located in Skopje, Bitola and Stip.

The three scenarios are presented on maps following relevant sections.

Scenario 1 – Central treatment – Incineration

In this scenario a single central treatment facility would be established equipped with an incinerator in the Skopje area, which are the major generating area of HCW in Former Yugoslav Republic of Macedonia. A suitable location for the incinerator will be at Drisla Landfill replacing the existing incinerator.

The collection area covered by the treatment facility will be the whole of Former Yugoslav Republic of Macedonia.

Collection and transportation of HCW in the Skopje area could for practical reasons take place as currently provided by PE “Komunalna Higijena” – Skopje, using a combination of small trucks or vans providing collection service towards the smaller HIs and larger trucks used by PE “Komunalna Higijena” – Skopje for collection and transport of the standard plastic containers on wheels from the central storage facilities at hospitals and health centres.

Outside the Skopje area the 15 general hospitals and the 32 health centres will function as collection points for HCW generated in the smaller HIs in their respective areas. Received waste at the general hospitals and the health centres will be stored in the respective central storage facilities until transport to the treatment facility is carried out. Transport will take place minimum once a week by a company having the proper permit and license to carry out transport of hazardous waste. The central storage facilities at hospitals will be cooled with maximum temperature of 8 °C, while this is not necessary for storage facilities at the health centres.

Scenario 2 – Central treatment - Autoclaving

In this scenario a single central treatment facility will be established equipped with an autoclave in the Skopje area, which are the major generating area of HCW in Former Yugoslav Republic of Macedonia. A suitable location for the autoclave could be at the Clinical Centre - Skopje as there is no severe health or environmental impacts from the autoclave process.

Separation, storage and collection of health care risk waste at hospitals and other HIs will take place as described above.

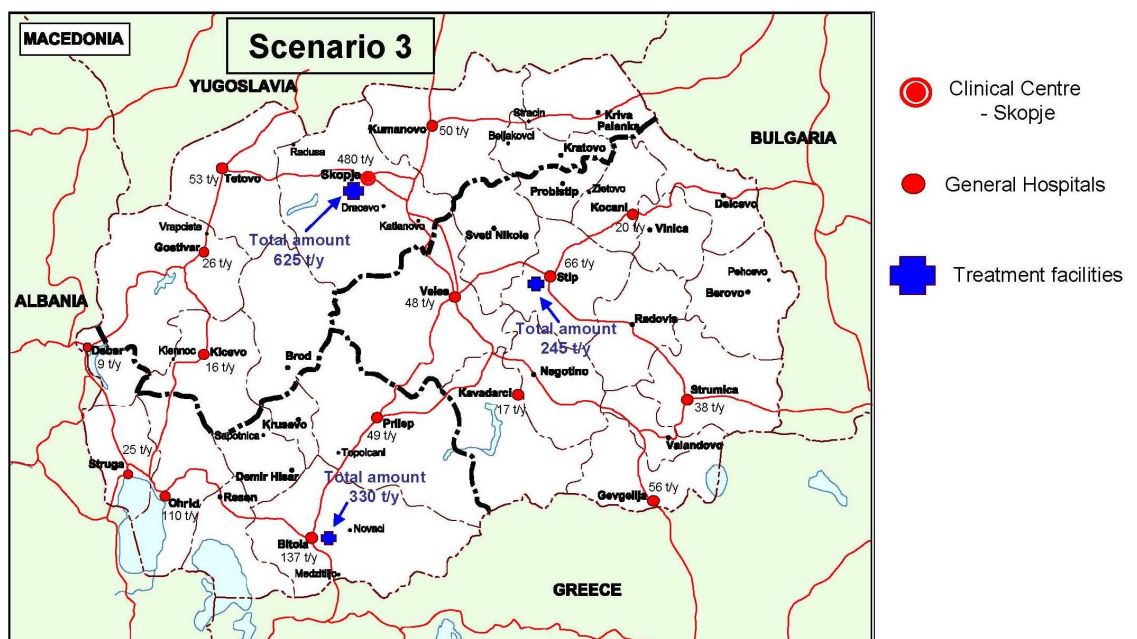
Schematic map of proposed HCWM scenarios



Scenario 3 – Decentralised treatment – 3 autoclaves

In this scenario three autoclaves will be established, each covering the following general hospitals and health centres functioning as collection points for their respective areas:

- One autoclave located in Skopje at the Clinical Centre covering the Skopje area plus the general hospitals located in Kumanovo, Tetovo, Gostivar and Kicevo, and the health centres in Skopje (2), Kumanovo, Kratovo, Kriva Palanka, Tetovo, Gostivar, Rostusa, Kicevo and Brod.
- One autoclave located in Bitola at the General Hospital covering in addition the general hospitals located in Ohrid, Struga, Debar and Prilep, and the health centres in Bitola, Ohrid, Prilep, Krusevo, Demir Hisar, Resen, Struga, Vevcani and Debar.
- One autoclave located in Stip at the General Hospital covering in addition the general hospitals located in Kocani, Veles, Kavadarci, Strumica and Gevgelija, and the health centres in Stip, Kocani, Vinica, Delcevo, Probstip, Sveti Nikole, Veles, Radovis, Berovo, Pehcevo, Negotino, Kavadarci, Strumica, Valandovo and Gevgelija.



Separation, storage and collection of health care risk waste at hospitals and other HIs will take place as described above.

5.2.1 Investment and Operational Costs

The data requirements for each of these strategic options and related scenarios are substantive and are to be collected for a period which exceeds the duration of this project and should be put in a special HCW database. This database will refer to the various hospitals and clinics (location, number of beds, generated HCW and composition, in-house separation and/or treatment, storage facilities etc.), and finally - cost profiles.

The investments and operational costs should mainly be determined by the type (cooled) and capacity of the transport trucks. These vehicles have to be newly procured. It is perceived that most of the procurement will coincide with the procurement of all other equipment (special containers, bins, coloured bags) required to establish a well functioning national HCW system.

There should be nationally recognized responsible authority of those procurements. At present two ministries are competing the responsibility - the Ministry of Environment and Physical

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Planning and the Ministry of Health. Furthermore, the ownership issues are complicated by the position of the Operator of the existing incinerator - the City of Skopje Public Enterprise "Drisla". This position is outside any law, therefore the institutional set up of the present collection, transportation and incineration arrangements between the Ministry of Health, private health care institutions and the Operator "Drisla" should be entirely revised.

Unit Costs, based on incremental cost analysis for final disposal and transporting in MKD / Euros per metric ton will depend on the delineation of the region and incinerator site location(s); geographical location(s) where the maximum HCW loads will cover the least distances will be considered for locating either storage (re-loading) places, or regional incineration facilities.

Below the cost elements of the future analyses are listed:

- **Capital Investment Costs (CIC)** for treatment facility (one or three) and healthcare institutions respectively covering buildings and plants, storage facilities, mobile equipment (e.g. collection trucks and vans), collection equipment for medical waste (e.g. containers and other reusable receptacles), etc., including depreciation of investment costs over the expected lifetime of the investment.
- **Fixed Operating Costs (FOC)** for treatment facility and healthcare institutions respectively covering annual maintenance costs of buildings and stationary and mobile machinery, plant and other equipment expressed as fixed percentages of the capital investment costs, and labour costs;
- **Variable Operating Costs (VOC)** for treatment facility and healthcare institutions respectively covering energy and other consumables, including non-reusable receptacles such as plastic bags and sharps boxes, treatment and disposal of part of the medical waste outside the system (e.g. chemical and radioactive waste), and final disposal of treated medical waste at landfills. In this sheet the disposal costs for non-hazardous healthcare waste (similar in composition to municipal waste) is also included. Revenues for selling of recyclable materials such as separately collected paper, cardboard, etc. can also be included in the calculation.
- **Transportation Costs (TC)** covering direct fuel costs in connection with both the "internal" and "external" collection and transport of medical waste. Maintenance of trucks and vans and wages for drivers should be included under the Fixed Operating Costs (FOC) above;
- **In-direct Costs (IDC)** in healthcare institutions covering annual expenditures for planning, training, monitoring and reporting, and the important use of signboards, posters, pictograms, colour code stickers for HCW identification, etc.;

The final cost assessment will have to take into consideration the alternative transport costs for variant locations of the treatment and/or storage facilities.

Criteria to be taken into account when selecting the site for either incineration or storage (cooling) facility are as follows:

- Accessibility.
- Distance from healthcare facilities.
- Distance to sensitive areas.
- Future development plans for the area.
- Possibility of buying the land.
- Proximity to cultural and historical sites.
- Noise and dust impact on nearby areas.
- If resettlement is an issue, the extent to which it is needed.

- Reliability of the power sources to run the treatment facility.

Finally, for the most favoured option the analysis should be carried further to highlight a feasibility assessment for the country.

The implementation phase will ultimately lead to (preliminary) specifications for the collection, transport and/or transfer, and final disposal system for regions to be established.

5.2.2 Assumptions and Risks

In order to set favourable conditions for implementation of the Health Care Waste Management Strategy stakeholders should assign staff and allocate resources. The institutional reform is of utmost importance, whereas financing of in-premises and beyond premises health care waste handling is crucial. General assumptions and risks highlighting the on-going approximation process as well as likely causes for hindering of particular achievements are given below.

Specific risks relating to the implementation of the HCW Strategy are formulated as follows:

- Existing inadequate and/or unreliable available data on all mentioned types and volumes of HCW. It is assumed that necessary relevant data are not recorded by waste generators, due to the present lack of proper health care waste segregation.
- Not all relevant main stakeholders (relevant authorities, hospitals/clinics, private waste collectors/service providers, polluting industries, hospitals, NGO's etc.) will give their full cooperation or react positively in providing necessary information and data.
- Not sufficient qualified representatives of the (main) stakeholders will be involved in the implementation of the HCW Strategy.
- There is a risk that the required collection/disposal fees will ultimately exceed the willingness of the hospitals/clinics (e.g. 'the polluters') to pay for all the costs involved.

Prior to the establishment of the national system, the first step towards improvement of the present practice at generator's level will be development of management plans for large Health Care facilities (as the threshold for planning and reporting has been set in the legislation at 50 kg/year of hazardous waste generated) in both the public and private sector.

As start up of this process may be considered the filling in the questionnaire which has been delivered upon the national survey (January 2007), in which present deficiencies are being reflected by leaving blanks under specific items.

5.3 Institutional arrangements

A suitable management organisation must be established for the responsibility for and operation of the future medical waste management system. It will cover both the "internal" (segregation, internal collection, temporary and regional HCW storage centres) and the "external" management (collection from regional storage centres up to the final disposal point(s)).

5.3.1 "Internal" Management organization

It is proposed that collection of HC waste from the individual healthcare institution and delivery to the central storage facilities established at all general hospitals and health centres (total number of 47) shall be organised on an "internal" (regional and/or sub-regional) basis; In cases where a town has both a general hospital and a health centre, an agreement must be made who takes care of this primary collection service from ambulatories, private medical practitioners, etc. **The general hospitals and health centres can also decide to tender out the collection services to a private company having the proper permit and license to carry out transportation of hazardous waste. In**

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this way the central storage facilities will act as collection points for medical waste in their respective areas and this management system will be identical in all three proposed scenarios.

A special arrangement for the primary collection service could be considered for Skopje, due to the fact that PE “Komunalna Higijena” – Skopje already is performing this collection service. **In this case the existing contracts between PE “Komunalna Higijena” – Skopje and HIs located in the Skopje area must be revised in accordance with the change in services being provided and the company must obtain a proper permit and license for collection and transport of hazardous waste.**

The costs of establishing and maintaining proper storage facilities at general hospitals and health centres, as well as the costs for purchase maintenance and operation of a sufficient number of small vans or trucks to be used in the primary collection service, should be incorporated in the economic calculations as costs concern the healthcare institutions directly, together with other internal costs such as investments in small plastic containers on wheels, receptacles, etc. and use of consumables in the form of plastic bags, sharps boxes, etc.

5.3.2 “External” management organisation

When it comes to the collection of health care waste from the central storage facilities and subsequent transport to treatment facilities, the treatment itself and final disposal of the treated medical waste an “external” management organisation should be considered.

No matter how the “external” management organisation is established and no matter which scenario is considered, the following duties of the management organisation will be of universal nature:

Practical duties:

- Collection and transport of HCW from central storage facilities belonging to general hospitals and health centres (total number of 47 in the whole country);
- Registration and reporting of all waste types and amounts collected including preparation of proper Waste Transportation Lists to be used as consignment documents;
- Division of waste collected, for treatment at the medical waste treatment facility and/or for treatment and disposal at other treatment/disposal facilities;
- Operation of the medical waste treatment facility (incinerator or autoclave(s)) including all necessary maintenance, monitoring and reporting activities;
- Transport of medical waste treatment residues for final disposal including registration of types, amounts and final destination.

Management duties:

- Preparation of annual budgets on all costs related to the operation and maintenance of the “external” medical waste management system;
- Determination of corresponding tariffs to be paid by medical waste generators being serviced by the system and assuring approval of such tariffs;
- Daily accounting/bookkeeping and based hereon issuing of invoices at regular intervals to the medical waste generators being serviced by the system and assure that invoices are being paid;
- Office and staff management;
- Reporting of all relevant financial, technical and environmental aspects to the owners of the medical waste management system and to the responsible authorities (MoH and MEPP).

5.3.3 Role of the private sector

Private sector participation in healthcare waste management is possible at different levels. At the simplest level, the private sector may be subcontracted solely to provide waste transportation services

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to individual healthcare facilities. At the other end of the spectrum, the private sector may sign a contract to Build, Operate, and Transfer (BOT) or Build, Own, and Operate (BOO) an entire HCWM treatment or disposal facility.

The private sector can play a significant role in providing waste treatment and disposal services if the contract establishes a clear set of rules about the division of responsibilities between the parties involved (i.e. regulatory authority, healthcare facility and private operator). The essential conditions for private sector participation are transparency, competition and accountability. Adequate budget provisions are also required at the healthcare facility or the local authority level to pay the private operator.

5.4 Conclusions

Based on present trends and the assumption that the quantity of HCW to be disposed would rise due to future improvements of the HCW management itself, the design capacity of a future national HCW handling and treatment system should be 30% above the current generated amount of HCW in order to have a sufficient capacity during the coming 10-year period. The design capacity of the HCW treatment system should therefore be approx. 1,200 tons/year.

One of the main strategic and financial questions is whether, only one central incinerator (i.e. at the Drisla landfill) is the optimal solution for the final disposal of the HCW, generated in the hospitals and clinics in Former Yugoslav Republic of Macedonia, or whether the establishment of several smaller regional incinerators is a more cost effective solution. It is clear that the investment costs and operational costs will play a decisive role.

Therefore a few logistical and operational scenarios should be developed, in order to assess the various options. The feasibility of in-hospital treatment options - e.g. autoclaving / disinfection-sterilisation - for certain HCW streams should be assessed as well; **however there will always remain a considerable waste fraction for which incineration seems to be the preferred option. For these quantities it is assumed that the export may be a better solution than selecting the incineration which is more costly than autoclaving.** This assumption was proven to coincide with the opinion of stakeholders (see Chapter 5 "National Workshop").

The following three development scenarios for treatment of HCW have been selected for further investigation in the present HCW Strategy:

- Scenario 1: Central treatment in one incinerator located in or nearby Skopje;
- Scenario 2: Central treatment in one autoclave located in Skopje;
- Scenario 3: Decentralised treatment in three autoclaves located in Skopje, Bitola and Stip

5.4.1 Centralized versus decentralized option

A number of criteria for evaluation of the two proposed options - a centralized versus decentralized option have been analysed. These are given in the Table below:

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Table 11 Advantages and disadvantages of the centralized and decentralized option

Alternative	Advantages	Disadvantages
Centralized	<ul style="list-style-type: none"> – Simpler design, construction and commissioning – Less problems with land acquisition – Easier inspection over the operations – Same tariffs for all system users 	<ul style="list-style-type: none"> – Low flexibility – High transport costs for remote hospitals
Decentralized	<ul style="list-style-type: none"> – Lowering of transport costs – Higher flexibility – Possibility to implement various institutional models 	<ul style="list-style-type: none"> – Longer period for the start up of operations due to the implementation of three independent projects – More complicated inspection – Three independent systems

For the purpose of comparison of the three scenarios, the following rating system is used with the result presented in table below (3: Very satisfactory, 2: Satisfactory, 1: Less satisfactory, and 0: Unsatisfactory):

Table 12 Evaluation of proposed scenarios

Scenario	Evaluation Criteria					
	Organisation	Treatment technology	Environmental legislation	Costs	Lifespan	Acceptance by the population
Scenario 1 Centralised system Incinerator	2	3	1	1	3	1
Scenario 2 Centralised system Autoclave	3	2-3	2-3	3	3	3
Scenario 3 Decentralised system Autoclaves	2-3	2-3	2-3	2-3	3	3

Costs (both investment and operational) for the first option as well as the environmental legislation (absence of a regulation transposing the Directive 2000/76/EC and the more stringent requirements concerning the IPPC) in tandem with the likely low acceptance by the population render the first option as the least favourable, although as a treatment technology it gets the maximum score. Further, the result of the rating points shows that Scenario 2 rates the best, while the third option is next to it.

The centralized option on the other hand, proves to be less flexible and involves excessive transport costs for the remote hospitals (see table 11, Advantages and disadvantages of the centralized and decentralized option). Therefore, the national stakeholders will have to make a final (political) decision on the future Health Care Waste Management concept.

There should be a nationally recognized responsible authority for procurements related to an improved HCWM system. At present two ministries are competing for the responsibility - the Ministry of Environment and Physical Planning and the Ministry of Health. Furthermore, the

responsibility issues are complicated by the position of the Operator of the existing incinerator - the City of Skopje Public Enterprise "Drisla", which is operating the existing incineration outside the legal conditions set in various acts and contracts.

With the Scenarios 2 and 3 there is a possibility to abandon present practice (and especially to exclude the PE "Drisla" from the institutional set-up which goes against the law, while there isn't any political will to change the situation). Taking over the entire system by the HIs would further contribute to setting more equitable and transparent tariffs. The private sector can be invited to take part presumably in the "external" collection and transport; an option for consideration is outsourcing of the HCW treatment to a private operator.

In order to set conditions for implementation of the Health Care Waste Management Strategy, stakeholders should assign staff and allocate resources. The institutional reform is of utmost importance, whereas financing of in-premises and beyond premises health care waste handling is crucial.

During a broad stakeholder communication the final decision on the HCWM scenario will be made, aiming at setting institutional and financial pre-requisites for financing of the entire system.

6 WORKSHOP ON THE NATIONAL HEALTH CARE RISK WASTE MANAGEMENT STRATEGY

The Draft of the National Health Care Waste Management Strategy was disseminated to various stakeholders at 18th of December in Ohrid. Invitees were selected in cooperation with the MEPP and the MoH (SIHP), representing the largest HIs, potentially those which would host the regional treatment facilities, as well as hospitals potentially serving a central storage point for smaller HCW generators. Selected HI received the invitation enclosed with the agenda, travel form for identification of the participant and an Executive summary of the last version of the Report as of November 2007, translated in Former Yugoslav Republic of Macedonian language.

Representatives of the Health Care Institutions appeared to be those who were directly involved in the HCWM on a daily bases: main nurses and rarely persons being responsible for either emergency response or infections control. There were also two Directors of Health Care Centres - from Kavadarci and Kocani. In addition, the Ministry of Environment was represented by two participants and the Ministry of Health appointed one representative from the Institute for Health Protection.

There were four different aspects of the HCW Strategy presented and discussed: The Baseline, The Regional Approach, the Alternative disposal methods and The Financing of the future HCWM System. Participants were predominantly interested to comment on the issues being part of the present situation, while their opinion on the proposed approaches they could not express immediately, without consulting some upper decision level at their institution.

The following discussions are the most relevant as a workshop output showing the direction and future steps towards the adoption of the Strategy as a tool of stakeholders to work on the improvement of the current situation:

Baseline.

The participants confirmed the data as being presented as a baseline. They emphasised that the main nurses are responsible for the segregation of the HCW in health care institutions. Segregation takes place at the source (diagnosis, laboratories, preventive, curative and palliative treatment of patients, research etc.). Once the waste is being separated at two main streams (non-hazardous-municipal like and hazardous, including also sharps), it is taken by the staff responsible for maintenance of the hygiene and transferred to the storage points, mainly being located in the outdoor area of the hospital's facilities. Various types of receptacles are used and often the medical staff is unable to use standardized (and approved) boxes, due to the high costs. Improvising is done with PET bottles serving as boxes for sharps, and in the absence of special yellow bags for infectious waste yellow coloured labels with the infectious symbol are put on black plastic bags. Not always racks are available and trolleys are not used for the internal transfer of the waste from the source to the storage point.

All the participants agreed that it is not possible to report on the generated quantities since there isn't any record keeping so far. Although the regulation on the form and content of the journal for waste handling, the forms and content of the forms for identification and transport of waste and content of forms for annual reports for handling waste is in place, hospitals do not comply with these requirements. Main reason for this is the divided responsibilities between the State Sanitary Inspectorate (responsible for supervising the segregation) and the State Environmental Inspectorate (responsible for the keeping of records after the segregation). However, the weak capacity of the hospital staff must be added to the mentioned reasons.

Another gap anticipated is the involvement of the State Communal Inspectorate being responsible for the supervision of the collection and transport of the non-hazardous HCW (municipal-like), while in most cases mixed HCW (hazardous and non-hazardous) is collected and transported by the Public Enterprises, having no license (and capacity) for the performing of the activity. The insufficient collection

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frequency (especially in smaller towns) was reported by the participants. This is another argument to change the current practice and to look for alternative collection/transport providers.

Also, the State Environmental Inspectorate is not explicitly authorised by the current legislation for the supervision over the transport of the HCW. Participants agreed on the need to point out these weaknesses of the legislation in the HCW Strategy more clearly; in addition, they suggested stipulating the training requirements for respective Inspectorates, including also the State Veterinary Inspectorate, which is authorised for the same duties as the State Sanitary Inspectorate for the HCW with the animal origin.

Another issue being discussed was the need for the internal planning for the HCWM at hospital level. The Main Nurses may not be assigned with such duties and therefore Waste Managers must be appointed by the large generators. The same person may be assigned with the responsibility for Emergency responses and dealing with spillages. It was stated by participants that the staff do not declare any injuries during the handling of the HCW (especially with sharps). Also, there is some medical staff that refused to obtain vaccination for Hepatitis B and C. Training of either Managers or workers having of any direct contact with HCW should be anticipated as well.

Planning hierarchy was also discussed and it was agreed that Waste Managers should oversee the implementation of HCWM plans, while there should be technical staff being directly in charge of the organizing of the HCW handling, record keeping and delivering of the previously segregated, packed and labelled waste to the collection/transport company. High management staff of hospitals should be aware of the complexity of the HCWM by means of more frequent inspections of responsible bodies.

Regional Approach

There were no major comments concerning the proposed regional approach. Participants agreed that the organization of the future HCWM system is in the hands of high decision making levels. The representative of the Stip Health Care Institute stated that in her understanding the assignment of the responsibility to the HIs and General Hospitals for the collection of HCW from smaller generators is premature; the approach which was presented sounds logical, but the national-wide system should be built step by step.

In the view of participants, the main issues for urgent resolution are the improvements in the internal planning including the appointments of the HCW Managers, aimed at better segregation of either non-hazardous or hazardous HCW. Recycling of paper, plastics and other commodities is regarded as an immediate benefit and contribution to the better financial performance of hospitals.

Once the inspections would be more stringent, (concerning the enforcement of the new regulations) the hospitals will have to consider ways to comply with the regulations. In this direction the State Environmental Inspectorate must penalize the Public enterprises for their collection of mixed HCW. It will, in turn, force the hospitals to look for other transporters and alternative disposal of the HCW. It will create a market for licensed transporters for hazardous waste (including the HCW) and the improvements will take place. The participants agreed that the key for the success of the regional story is the inspection of the all chains of the HCWM, from the segregation, storage, collection, transport and disposal.

The most urgent follow-up of the Strategy is considered the training of the three Inspectorates sharing certain responsibilities over the enforcement of the laws regulating the HCWM as a whole.

Alternative disposal

Most of the participants agreed that the present HCW quantities are too small to justify investments in either a central or regional incineration facility. Furthermore, Former Yugoslav Republic of Macedonia can not afford to comply with the continuous changes of the EU legislation concerning the lowering of the emission thresholds. Therefore, the **autoclaving was preferred as a disposal option**. It would

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influence a dramatic change of the current HCWM system, especially concerning the closure of the existing incinerator and the termination of the contract between the MoH and the PE "Komunalna Higijena" from Skopje.

Participants expressed their concern about the timing of the closure of the "Drisla" incinerator, which, although causing risks, is a kind of a solution for the HCW for the Skopje and Kumanovo area. Its closure must follow the purchase of at least one (regional) autoclave) and it was commented that, as always, Skopje (and Kumanovo) will get to the solution sooner than the other regions. Therefore, the Strategy must recommend not only the suggested solution, but also the schedule for the implementation of the regional approach.

As for the chemical and other waste types which can not be treated by autoclaving, participants agreed that a national-wide solution for the management of the hazardous waste should be anticipated, whereas the export (from the environmental point of view) is maybe the best solution. MEPP and MoH, together with other Ministries sharing problems with some hazardous waste (Ministry of Economy, Ministry of Agriculture, Forestry and Water Economy, Ministry of Transport etc.) should conduct cost-benefit analyses concerning the national disposal of the hazardous wastes (including those originating in the health care) versus the export scenario.

Financing of the HCWM

Participants noticed the interrelation between the regional organization and financing issues. They expressed their concerns on the need to pay a tariff for the collection of the non-hazardous (municipal waste) to the Public enterprises and a tariff for the collection & transportation & disposal (autoclaving) to the regional centre (hospital) or to the private company having the contract with wither individual hospitals or regional organizations.

They agreed that the most important issue is the transparent setting of tariffs as a means of convincing of the hospital management staff. Even if the inspections would be active, participants agreed that the reduction of the HCW for disposal will not be always environmentally friendly. A regional organization, which would monitor over the compliance with the legislation, including the regular payment for the HCWM would be a key for success. Also, single hospitals would not be let alone and the regional system might lobby for initial subsidising for those with weaker financial capacities.

Regional subsidy programmes should be initiated with the support of the ministries in charge.

Conclusions from the Workshop:

- All the participants felt that having such a Strategy is only the first step in the process for solving the accumulated problems in the health care sector as a whole, and for the improvement of the HCWM issues in particular.
- Awareness on the need to organize the entire system from the segregation at source, through the storage, collection, transport and disposal is not satisfactory, especially when it comes to making decisions at the high management level.
- The most important issues to integrate in the Strategy are as follows:
 - Forbid the Public enterprises to collect/transport mixed HCW; this should be integrated in the current Regulation on the Manner of Handling HCW, Labelling and Forms for Handling HCW and on Types of HCW for which Processing is prohibited;
 - Appoint and train HCW Managers to conduct internal planning and monitoring over the implementation of the HCWM plans;
 - Train Inspectorates;
 - Initiate regional HCWM systems and establish regional planning / financing, including the preparation of the regional subsidy programmes.
- Broad acceptance of the autoclaving versus the incineration has been expressed by the participants.

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- The schedule for the implementation of the Strategy should be prepared, allowing for gradual improvements in line with the affordability.
- Closure of the existing incinerator placed at the landfill "Drisla" in Skopje should be followed by the purchase of the autoclave serving the region in which the regional system would be established first. Once the system would become functional, the activity can be repeated for the remaining (two) regions.

7 CONCLUSIONS AND RECOMMENDATIONS

7.1 Immediate needs and proposed activities

As discussed in previous chapters, the transition from the present practice concerning the HCWM to a functional system in line with the EU policy and regulations should gradually allow for practical improvements in the following areas:

1. Policy formulation and planning at all levels: national, regional (healthcare area);
2. Organization and implementation of an improved internal HCW collection: segregation, labelling/packaging and storage; reinforcement of the existing reporting and introduction of reporting where it does not take place;
3. External collection to the storage points and transportation of HCW by licensed transporters;
4. Disposal in an environmentally safe manner (e.g. autoclaving);
5. Cost recovery of operations, meaning that the tariffs for municipal and HCW should be separated in a transparent way, while the following costs should be taken into account for the HCWM tariffs;
6. Inspection and enforcement of the legislation;
7. Public awareness and education of all stakeholders involved in the HCWM, including the general public.

Not all of above described areas for improvement can be tackled in the same time, nor the country may afford immediate actions which involve excessive costs for the hospitals and the society as a whole. Therefore, the timeline of activities to be undertaken should be planned with utmost care and within a climate of a broad consensus. However, it is not always possible in the given political environment and the Government must be given a clear guidance concerning the priority actions along which the main stakeholders should gather and decide on their implementation. In the following lines the most urgent activities towards an improved HCWM are elaborated.

7.1.1 Enhance internal waste handling

Prior to the establishment of the national system, the first step towards the improvement of the present practice at generator's level will be development of management plans for large Health Care facilities (as the threshold for planning and reporting has been set in the legislation at 50 kg/year of hazardous waste generated) in both the public and private sector.

Plans they have to take duly into account HCWM principles, being elaborated in Chapter 4. Training of involved personnel should follow, addressing the main issues as described below in paragraph 7.1.1.2.

7.1.1.1 Appointment of waste managers

Based on Plans the internal monitoring and reporting must be carried out. It can be carried out only if Waste Managers at hospital level would be assigned, changing the current practice where the main nurses are involved both in planning and direct activities concerning waste segregation.

According to the Law on Waste, Waste Managers hold a high education from the technical sciences and they have to pass an exam. There isn't any specific course for Waste Managers.

By the law, Health Care Waste Managers are responsible for the overall planning of the on-site HCWM and for the performance the members of the technical waste teams involved in any chain of the HCW handling.

Although most of the activities towards an improved HCWM are regulated, the enforcement of regulations is lacking. It can be strengthened only if the inspectorates are provided with an appropriate

training. In addition, the political will to exert penalties is required. This is again in close relation to the public awareness on the risks associated with the inappropriate HCWM.

In the following text a possible outline of a broad capacity building is proposed. It is based on various experiences from other countries⁶.

7.1.1.2 *Training of involved personnel*

It is widely acknowledged that training is an essential component of health care waste management. This is partly because it is often assumed that lack of adequate knowledge is the reason behind poor waste segregation practice in the health care sector. Training provision in the public sector in the Former Yugoslav Republic of Macedonia for HCWM has been insufficient and fragmented.

The experience from other countries shows that at least two different training programmes as part of the capacity building programme of the health care personnel should be developed and conducted.

The first training programme is a programme of on the job informal education to teach attitudes, knowledge and skills essential to the implementation and maintenance of a new HCWM equipment system. The second programme is an intensive training course for Health Care Waste Managers.

The importance of understanding the role of training within the broader context of capacity building and the importance of using qualitative research methods to collect information about training needs should be understood.

Identifying training needs

It is tempting to believe that training is the answer to problems that arise in HCWM in health facilities. However, often the reason for poor performance may not be because of a lack of training. For example, an over filled sharps container could have many root causes, such as staff not knowing when to close the sharps container at three-quarters full, the wrong sized sharps container at the point of generation so that it is filling too quickly, an inadequate supply of sharps containers to the health facility so that it is not possible to replace a sharps container on time, and poor ordering and delivery of sharps containers to wards from health facility stores etc. It is critical for successful training interventions in HCWM that training needs are identified alongside other capacity needs that can not be addressed through training.

This is done by conducting a “performance discrepancy analysis”. This approach describes “capacity” in terms of “performance”. Performance gaps are associated with equipment failure and inadequacies, poor management, human resource issues, training and policy gaps. Capacity building therefore ensures that the “hard” and “soft” sides to development programmes are sufficiently addressed for a successful implementation and a long-term sustainability.

A performance discrepancy analysis identifies areas of performance where there is less than optimum functioning. These areas of discrepancy or under-functioning can also be described as “gaps”. For HCWM, the three critical commonly identified gaps that are relevant to training are:

- knowledge gaps;
- skills gaps; and
- attitude gaps.

However, in addition to these areas other important areas are known to impact on the delivery of HCWM systems and include the following:

- inter-staff relations;

⁶ Dr André Swart, School of Public Health, Technikon Witwatersrand

- worst case scenarios when the HCWM system breaks down completely;
- technology gaps;
- policies and procedures gaps; and
- organisational, management and supervisory gaps.

Each area of discrepancy is summarised in Box 4. For a successful training intervention it is essential that the correct knowledge, attitude and skills gaps are identified. Secondly trained health workers then need to operate in a system where their performance is not undermined by other gaps in the system. For example health workers can be trained to close sharps containers when three quarters full, but this must be supported by a policy that enforces this standard. It was clear upon the Workshop that the purchasing policy in hospitals is constrained by inadequate supply of receptacles due to savings pursued by the high management staff. This gap must be addressed throughout the trainings.

Box 4: The performance discrepancy analysis for HCWM in a health facility

Knowledge gaps: There is a set of basic information that all categories of health employees should know about HCWM. This includes basic knowledge of types of health care waste, segregation of health care risk waste, occupational health and safety issues, use of specific equipment etc.

Skills gaps: Skills are distinguished from knowledge by being something “you can do” rather than something “you know”. Skills include correct use of equipment and the implementation of procedures, for example, closing liners correctly, loading sharps correctly in sharps containers and completing an incident report form.

Attitude gaps: For effective HCWM it is essential that health employees hold positive attitudes towards care of the environment, occupational health and safety and teamwork.

Worst-case scenarios: This category describes situation when the performance of the HCWM system is seriously undermined and jeopardised. For example, there is no collection by the service provider, or no provision of equipment.

Inter-relations: Inter-relations is concerned with staff relations, especially those that adversely impact on the performance of the HCWM system such as poor communication between general assistants, nurses and doctors.

Technology gaps: The specifications, standards and appropriateness of equipment all impact on the performance of the system.

Policies and procedures gaps: Policies, guidelines, procedures and/or codes of practice are essential to support any HCWM system. Policy and procedure gaps happen where policies and/or procedures are missing. Often policy and procedures for HCWM are written into one document called a *Code of Practice*. Another option suiting to the Macedonian case would be integration of these in the waste management plan.

Organisational, management and supervisory gaps: These gaps relate to the management function as a whole. The Code of Practice referred to above would normally be expected to describe the organisational structures necessary to support HCWM at a health facility level. This includes roles of senior management, all categories of staff, the role of the occupational health and safety committee and the service contract with the service provider.

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Use of qualitative research methods

Information for a performance discrepancy analysis is collected through use of a number of research methods. This includes a review of all relevant documentation, on site inspections and completion of audit forms and checklists and key informant interviews with senior and middle management.

Target health care officials are as follows:

- focus group with senior and professional nurses including ward managers;
- focus group with auxiliary and enrolled nurses;
- focus group with doctors; and
- focus group with general assistants and ward helpers.

The purpose of the focus groups is to do the following:

- explore the range of factors that impact on the behaviour and practices of staff;
- explore the knowledge of staff about health care waste management;
- explore the attitudes to health care waste management; and
- understand the roles and responsibilities in health care waste management.

The advantage of using qualitative methods is that it allowed the researchers to explore with a large number of health workers the range of factors that impact on HCWM. A qualitative research is usually done when aspects of a topic are poorly understood. The focus groups should be conducted by an independent researcher and by the capacity building consultant. A brief information should be prepared for each category of health staff to be interviewed.

Results from the qualitative research relevant to the design of the training interventions

A possible range of results may include the following:

- usually the best knowledge on HCWM is shown by the lowest level of employees, which is owed to the fact that doctors do not see their involvement in any part of the HCWM;
- there is a level of poor practice in HCWM that is related to negligence that probably has its root causes in broader aspects of low health worker morale in the public sector;
- multidisciplinary training is important overcome communication barriers;

The design of the capacity building programme

The capacity building programme should address the gaps identified primarily through the development of appropriate training programmes. However, there are usually three significant performance gaps as follows:

Worst-case scenarios where the HCWM system breaks down completely:

- The buying department leaves the hospital stores without equipment for waste collection this appears because of a breakdown in timely ordering or a problem with the supplier;
- The distribution of equipment around the hospital is not always reliable and therefore there is stockpiling of cardboard boxes and other equipment in the wards;
- The budget does not allow for the procurement of sufficient bins for general waste and health care waste at the point of generation;
- Inappropriate colour bags are supplied which results in incorrect colour coding.

Policy and procedures

Although in the questionnaires the most of hospitals reported the existence of such procedures, it appeared that this is not the case. It is essential that new procedures are developed to support the improved HCWM system.

Organisational, management and supervisory gaps

Usually, there is no internal or external auditing of the HCWM system. Supervision of HCWM line functions in the hospital and clinic wards and departments is very poor and there is no internal performance monitoring of the HCWM system.

The approach to capacity building might have seven elements of which training is one part. The overall approach to capacity building should ensure that the capacity building programme complements the introduction of new equipment.

The capacity building programme should involve:

1. Provision of new policy and procedures for HCW Management written as a Code of Practice
2. Introduction of improved monitoring and reporting
3. The introduction of a dedicated Health Care Waste Manager and an Assistant
4. Knowledge, attitudes and skills training
5. Awareness activities
6. On the job skills coaching
7. Evaluation of capacity building activities

7.1.1.3 Training of the three Inspectorates

In order to set conditions for implementation of the Health Care Waste Management Strategy stakeholders should assign staff and allocate resources; of utmost importance is the institutional reform whereas financing of in-premises and beyond premises health care waste handling is crucial.

Next step would be carrying out of specific trainings and campaigns aiming to raise awareness and capacity on HCWM throughout the country. A crucial moment is to train the Inspectorates (SEI, SSI and SVI) which are the main stakeholders to contribute to the above said reforms. As the list of topics to be covered by the training for hospital staff covers the 7 most important issues, all of them are to be a subject for inspection. Examples of inspection include:

- Inspection if there is a Code of Practice or a Waste Management Plan for the hospital
- Inspection if the record keeping and reporting takes place
- If a Waste Manager is being appointed and if he/she is qualified for the job (proof that he/she passed the exam)
- If the purchasing policy for receptacles is adequate, i.e. the minimum packaging and labelling is complied with
- if the storage place is equipped appropriately
- etc.

An additional cross checking of the legislation against the regulation of these authorities of the inspectors is to be made.

7.1.2 Establish regional HCWM

In addition, there should be a regional planning initiated aiming to effectuate the three HCWM systems gravitating to the regional treatment facilities (autoclaves). After a political decision is taken, the regional plans including the technical planning (collection, transport and disposal) as well as the financing schemes (including the user charges) should follow. Upon the fundraising supported by national allocation of the co-financing, there should be "elected" a nationally recognized owner of procurements related to an improved HCWM system.

The transition from the baseline - Skopje + Kumanovo incineration system and mixed municipal + HCW dumping system in remaining municipalities towards the environmentally safe (regional) operations can be done in two ways:

1. Hospitals in other municipalities may organize separate collection and transportation to Drisla similarly as it is done in Kumanovo (the health care institute collects HCW from smaller hospitals and brings it to Skopje). Bearing in mind unfair negotiation of tariffs by the PE "Komunalna Higijena", the MEPP and the MoH should interfere asking for a new methodology for setting of tariffs; another instrument would be to establish a regulatory body which could oversee the setting of new tariffs for the transition period and for the period of the functioning of the new system, because the private sector could take over parts of the operations and the public authorities might need assistance with regard to the keeping the tariffs stable.
2. Hospitals in other municipalities may wait for a new (regional) autoclave and then start organizing the external collection and transportation; for this approach it is essential to start early enough to draft the legal documents regulating the relationship of institutions involved in the regional system: hospitals, transporters and the operator of the autoclave. These regulations must clarify the ownership (joint ownership of the autoclave by hospitals, private operator and owner of the both transportation system and the autoclave, or separate ownership over the transportation and the autoclave, etc.).
3. Following the establishment of the first region, the remaining parts of the country subsequently implement the remaining HCWM systems

7.1.3 Further elaboration of scenarios

The two scenarios (central and decentralized systems with autoclaving) should be elaborated in the following terms:

- Detailed cost estimates for the expenditures listed in paragraph 5.2.1, "Investment and operational costs";
- Operational / Institutional concepts (public enterprises, shareholding companies owned by hospitals, PPP or similar) along with the legal documents involving tenders, contracts etc.;
- Broad Public participation and consultation of the governmental bodies.

An advantage to have in mind originating from a PPP approach could for instance be to tender out the collection and transport services to a private waste management company having the necessary permits and licenses. The PPP concept can be further developed in the future to also comprise management of the treatment facility itself.

7.1.3.1 Solution for the waste which can not be autoclaved

As discussed on the Workshop, it appeared that the hazardous waste remains a huge problem in the country. A solution for a portion of it is the incineration; however, it is believed that these quantities do not prove an erection of an incinerator. Also, the acceptance of the incineration by the population is rather low. Therefore, it is anticipated that the entire hazardous waste quantities in the country originating from various sources shall be subject to exporting.

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7.2 Transparent setting of tariffs

The root of problems with regard to current tariffs seems to be the unclear institutional set-up of the Skopje HCWM system in which the contractual arrangements between the Ministry of Health and the City of Skopje are obsolete. It is expected that amendments of present laws, or issuing a new regulation (e.g. methodology on setting tariffs) and/or involvement of a regulatory body is the start for the solution of the problem.

If municipalities outside Skopje would undertake a separate collection / transportation of the HCW via abolishing the present contracts with the public utilities and contracting out licensed operators and joining the "Drisla" incineration system, this should be considered a transition measure only. The advantage of it could be the familiarization of hospitals with the additional fee to be paid for the separate collection/transportation of HCW and its incineration. An improved HCW segregation as well as initiation of recycling, being driven by the higher fee can be expected as well. Another possible approach would be to wait for the establishment of the complete system at once, along with the purchase / installation of necessary facilities and equipment. It may favour a more transparent setting of tariffs which can convince hospitals to join the new regional systems (if selected against the centralized option).

There isn't any institution appointed in the legislation for monitoring over the setting of tariffs in the public sector including the HCWM. As being discussed at the Workshop, an establishment of a regulatory body may be considered. This entity may not only supervise the health care waste management related tariffs (for internal, external collection / transportation and disposal) but it can oversee the setting of tariffs for other sectors, such as municipal waste management, water and wastewater management etc.

Taking over the entire system by the HIs would further contribute to setting more equitable and transparent tariffs. Private sector can be invited to take part presumably in the "external" collection and transport; an option for consideration is outsourcing of the HCW treatment to a private operator.

7.3 Enforcement of existing regulations which will make the institutions search for ways to comply with them

First task for the legislator, as discussed on the Workshop, is to address the prohibition for transportation of the HCW mixed with the ordinary household waste by the municipal utilities and its disposal at the present dumpsites. Participants pointed out that the most appropriate solution would be to amend the recently adopted Regulation on the Manner of Handling HCW, Labelling and Forms for Handling HCW and on Types of HCW for which Processing is prohibited. This has been outlined in the relevant paragraph of the Strategy 2.5 and 2.5.1. With such a measure the hospitals would be imposed to searching ways how to comply with the present Law on Waste, prohibiting the mixing of the municipal waste with the hazardous waste.

The crucial part of the enforcement of the legislation is the affordability to implement the system and the stringent practicing of the inspections.

The elements of the Action Plan have been set based on the project analyses and the recommendations of the workshop's participants. These are outlined below.

Most of the required actions may accompany the investments, such as the public awareness and the establishment the institutional set-up including the appointment of the operator(s) for the external transport and disposal. However, the training of Waste Managers and Inspectorates may start independently from the investment upon the available funding. The same applies for HCWM plans of hospitals.

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In the figure overleaf the scope of possible activities for the previously set groups of actions is given. The order of specific action coincides with the schedule for implementation. The timeframe and the precise determination of the responsibilities / authorities for the implementation of the Action Plan are not part of the Strategy. They should be dealt with a separate follow up project.

Table 13 Groups and order of activities towards an improved HCWM

Strategy Framework	Internal HCW Collection and storage	External collection & transportation	Disposal / Autoclaving	Cost recovery	Inspection / Enforcement of the legislation	Education and Public Awareness Raising
Approval of the HCWM Strategy	Appointment of a Waste Manager	Organize a central storage point for a number of hospitals in a municipality / sub-region	Select a location (preferably at the premises of the biggest HCW generator in the region)	Develop a methodology for setting of tariffs	Regular inspections within hospitals	Training of the Waste Manager
Development of HCWM plans of hospitals	Organization of the segregation, packaging/labelling, internal collection and storage at hospital level in accordance with the plan	Purchase suitable equipment (racks, ventilation, refrigerators etc.)	Develop the technical documentation, EIA and the urban plan (plus public consultations)	Appoint the institutions in charge of setting of tariffs (Ministry or a regulatory body)	Inspections on the reporting system	Training of technical staff in hospitals involved in the HCW
Development of HCWM regional plans	Purchase of bags, other receptacles, wheeled trolleys, containers, or carts that are not used for any other purpose	Make contract with a licensed transporter	Obtain a "B" IPPC permit	Set tariffs transparently	Inspections of the transport	Training of Inspectors of the SSI, SEI, SVI and the SCI
Participatory Planning Review	Setting conditions for an in-hospital central storage site	Prepare and deliver transportation consignment forms	Purchase and install the facility	Set incentives / penalties for non-paying hospitals	Inspections of the autoclave operations	Training of high decision making officials
Overseeing of the Strategy Formulation	Appointment of technical staff to implement the HCWM within the hospital			Penalize non-paying costumers	Inspections on illegal dumping of the HCW	Training of the staff operating he autoclave

ANNEX I

Questionnaire on Healthcare Waste (HCW) Management at Healthcare Facility level

1. The Healthcare Facility							
1.1 General information							
Name of healthcare facility:							
Address:				Telephone:		E-mail:	
_____				Fax:		_____	
_____				_____		_____	
_____				_____		_____	
_____				_____		_____	
Contact person(s) :				Title(s):		Telephone:	
_____				_____		_____	
_____				_____		_____	
_____				_____		_____	
Type of facility: (e.g. Clinical Centre, Specialised Hospital, General Hospital, Health Centre, Health Station etc.):				Number of <i>in patients</i> per year:		Patient days:	
_____				_____		_____	
Number of beds:				Number of <i>out patients</i> per year:		Note:	
_____				_____		A patient day is defined as at least eight continuous hours in residence in the facility in a twenty-four hour period during which the patient receives medical services	
Number of staff		Total	Medical doctors	Nurses	Nurses' aids	Sweepers	Others
_____		_____	_____	_____	_____	_____	_____
Owner of the establishment:			Public Health Institution:				
_____			Private Health Institution:				
_____			_____				

2. Medical departments / wards at the healthcare facility		
Type of department/ward	Number	Comments
General medicine		
Operational ward (OR)		
Gynaecology		
Obstetrics		

Paediatrics		
Gastroenterology		
Endocrinology		
Ear-nose-throat		
Oncology		
Pulmonary diseases		
Infectious diseases		
Haematology/Blood bank		
Radiology		
Pharmacies		
Laboratories (indicate type(s))		
Pathology		
Other		
Non-medical departments		
Type of department	Number	Comments
Kitchens		
Laundries		
Maintenance departments		
Stores		
Other		

Comments:

3. Segregation of waste in general	
Is healthcare risk waste (HCW) separated from non-HCW (ordinary waste) at place of generation?	

3.1 Information on HCW amounts and types				
<p>Note: If the separate fractions indicated in the column to the right are known, please state the amount.</p> <p>If the HCW is not segregated into fractions or the amount per fraction is not known, please state the total amount in the bottom line as an estimate.</p>	Waste fraction	Amount in kg per year	Amount in m³ per year	Number of bags/boxes per year Size of bags/ boxes (litre):_____
		- or	- or	
	Infectious waste			
	Sharps			
	Pathological/biological			
	Pharmaceutical waste			
	Genotoxic waste			
	Chemical/toxic waste			
	Heavy metals			
	Pressurized containers			
	Radioactive materials			
	Liquid waste			
Other				
	Total amount (all fractions together) of HCW per year			
Is the generated amount of HCW reported? If yes, how often and to what authority				

3.2 Information on non-HCW (ordinary waste) amounts and types			
Waste types	Amount in kg per year	Amount in m³ per year	Number of bags or containers per year Size of bags/ containers (litre):_____
<i>Note:</i>	- or	- or	
<i>Is waste separated for recycling?</i>			
<i>If yes, please state what types and approx. amount per year in the comments box below.</i>			
Non-HCW (ordinary waste) in total			
Other non-HCW (if relevant, state type)			

Comments:			

4. Types of collection equipment (receptacles) and packaging					
4.1 For Healthcare Risk Waste (HCW)					
<p><i>Note:</i></p> <p>Please use these numbers to indicate type and material where possible</p> <p>No. Material</p> <ol style="list-style-type: none"> 1. Metal bins 2. lined with plastic bags (PVC) 3. lined with plastic bags (non-PVC) 4. lined with other material 5. Plastic bins 6. lined with plastic bags (PVC) 7. lined with plastic bags (non-PVC) 8. lined with other material 9. Racks 10. with PVC bags 11. With non-PVC bags 12. Sharps boxes 13. Dedicated boxes WHO type or similar 14. Self-made sharps boxes 15. Other 	Waste fraction	Type and material (please use No. from column to the left where possible)	Size (Litre)	Total number of each receptacle in the healthcare facility in use	
	Not segregated				
	Infectious waste				
	Sharps				
	Pathological/biological				
	Pharmaceutical waste				
	Genotoxic waste				
	Chemical/toxic waste				
	Heavy metals				
	Pressurized containers				
	Radioactive materials				
	Liquid waste				
	Other				
	4.2 For non-HCW (ordinary waste)				
	Comments :	Type and material		Size (Litre)	Total number of each receptacle in the healthcare facility in use
<input type="checkbox"/> Metal bins <input type="checkbox"/> lined with plastic bags (PVC) <input type="checkbox"/> lined with plastic bags (non-PVC) <input type="checkbox"/> lined with other material					

	<input type="checkbox"/> Plastic bins <input type="checkbox"/> lined with plastic bags (PVC) <input type="checkbox"/> lined with plastic bags (non-PVC) <input type="checkbox"/> lined with other material		
	<input type="checkbox"/> Racks <input type="checkbox"/> with PVC bags <input type="checkbox"/> With non-PVC bags		
	<input type="checkbox"/> Other (indicate type)		

5. Marking of waste collection equipment (receptacles) and use of colour coding

Is all equipment for waste collection marked or labelled clearly indicating each type of waste?	
Are waste-specific colour codes used together with marking?	
Have all types of waste collection equipment fixed places at ward and facility level?	
Are the locations for waste collection equipment marked (label on the wall etc.)?	
Are instructive posters describing how to separate the waste in use and displaced in the different wards?	

6. Removal/emptying of waste collection equipment (receptacles) and storage containers

	Type of storage container and location, e.g. in special storage room, outside, etc.	Size (litre)	Total number of storage containers in the healthcare facility in use
Storage containers for healthcare risk waste (HCW)			
Storage containers for non-HCW (ordinary waste)			
How often the waste collection equipment (receptacles) is removed or emptied into the storage containers? <i>Note: If relevant, please make distinction between the different receptacles in use</i>			

7. Waste storage rooms or areas				
	Number	Area m ²	Storage temperature (C°)	Comments:
Storage rooms or areas for healthcare risk waste (HCW)				
Storage rooms or areas for non-HCW (ordinary waste)				
How often waste is removed from the storage rooms/areas?				
Are there any special procedures for storage of different types of waste, including liquid waste?				
How is the wastewater from cleaning and disinfection of the storage rooms/areas disposed off?				

8. Internal handling and transportation			
8.1 Transportation of waste within the premises of the healthcare facility			
	Types of trolleys, or similar, in use at the healthcare facility	Number of trolleys etc.	Size (capacity in kg or litre)
Healthcare risk waste (HCW)			
Non-HCW (ordinary waste)			
Other waste (please specify type)			
8.2 Transportation of waste away from the premises of the healthcare facility			
	Collection service performed by communal enterprise or private contractor	Type and size of collection vehicle used	Waste collection tariff MKD/kg (or m ³)
Healthcare risk waste (HCW)			
Non-HCW (ordinary waste)			

Other waste (please specify type)				
8.3 Use of protective clothing				
Is protective clothing used by sweepers and orderlies handling waste?				
Please describe type of protective clothing, e.g. face-masks, aprons, gloves, heavy boots, etc.				
8.4 Cleaning/disinfection of waste collection equipment				
Please describe how the waste collection equipment including trolleys etc. is cleaned / disinfected and how often including description of cleaning site (drain etc.). If disinfectants are used, indicate types.	Bins			
	Trolleys			
	Containers			
	Other			
9. Treatment of waste inside the health care facility				
<i>Note: If part of the waste is treated inside the healthcare facility prior to collection and transport away from the premises of the healthcare facility, please state type of internal treatment method, e.g. chemical disinfection, autoclaving, "decay-by-storage" of low radioactive isotopes, etc. If needed, please copy the form.</i>				
Internal treatment # 1		Type of waste	Amount in kg per year	Costs per year
Treatment method				
Comments:				
Internal treatment # 2		Type of waste	Amount in kg per year	Costs per year
Treatment method				

Comments:				
Internal treatment # 3		Type of waste	Amount in kg per year	Costs per year
Treatment method				
Comments:				

10. Treatment and disposal of waste outside the health care facility				
<p>Note: If the waste is treated at several places and by several methods, please fill in the information for each operator etc. below. If needed, please copy the form.</p> <p>In case of veterinary facilities please state how animal carcasses and operating theatre waste are disposed off.</p> <p>In case of pharmacies please state how outdated pharmaceuticals are disposed off.</p>				
Treatment/disposal facility # 1		Type of waste	Amount in kg per year	Costs per year
Treatment/disposal method				
Name of contractor				
Address of contractor				
Name of operator				
Address of operator				
Distance to operator in kilometres (approximately)				

Treatment/disposal facility # 2		Type of waste	Amount in kg per year	Costs per year
Treatment/disposal method				
Name of contractor				
Address of contractor				
Name of operator				
Address of operator				
Distance to operator in kilometres (approximately)				
Treatment/disposal facility # 3		Type of waste	Amount in kg per year	Costs per year
Treatment/disposal method				
Name of contractor				
Address of contractor				
Name of operator				
Address of operator				
Distance to operator in kilometres (approximately)				
Comments:				

11. Wastewater	
Treatment of wastewater	Method of treatment
Treatment at the premises of the facility	
Treatment at a public waste water treatment plant	
Pre-treatment at the premises of the facility and discharge to the public sewage system	
Other treatment of the waste water (please describe)	

Are some types of healthcare risk waste (HCW) disposed of together with the waste water? (please indicate type)	
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12. Training	
Does the facility arrange waste handling training of the staff regularly?	
Is training arranged for all new staff?	
How often is the staff trained including brush-up?	
Comments:	

13. Organisational issues	
Has the facility established a waste management organisation?	
Has the facility appointed a responsible person for waste management?	
Has the facility elaborated written procedures and or guidelines for waste handling?	
Has the facility established an infection control organisation?	
Has the facility appointed a responsible person for infection control?	
Has key personnel job descriptions incorporating waste and infection control issues?	
Comments:	

ANNEX II

List of healthcare institutions (HIs) which received questionnaires

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No.	PUBLIC HEALTHCARE INSTITUTIONS - UNIVERSITY SKOPJE
1.	Clinical Centre-Skopje
2.	Dental Clinical Centre-Skopje
3.	Clinic for Maxillofacial Surgery-Skopje
4.	Institutes of the Medical Faculty-Skopje

	PUBLIC HEALTHCARE INSTITUTIONS - HEALTH CENTRES
1.	Health Centre-Bitola
2.	Health Centre-Gevgelija
3.	Health Centre-Gostivar
4.	Health Centre-Debar
5.	Health Centre-Kavadarci
6.	Health Centre-Kicevo
7.	Health Centre-Kocani
8.	Health Centre-Kriva Palanka
9.	Health Centre-Kumanovo
10.	Health Centre-Ohrid
11.	Health Centre-Prilep
12.	Health Centre-Struga
13.	Health Centre-Strumica
14.	Health Centre-Tetovo
15.	Health Centre-Veles
16.	Health Centre-Stip
17.	Health Centre-Berovo
18.	Health Centre-Makedonski Brod
19.	Health Centre-Valandovo
20.	Health Centre-Vevcani
21.	Health Centre-Vinica
22.	Health Centre-Delcevo
23.	Health Centre-Demir Hisar
24.	Health Centre-Kratovo
25.	Health Centre-Krusevo
26.	Health Centre-Negotino
27.	Health Centre-Pehcevo
28.	Health Centre-Probistip
29.	Health Centre-Radovis
30.	Health Centre-Resen
31.	Health Centre-Rostuse
32.	Health Centre-Sveti Nikole
33.	Health Centre-Skopje
34.	Health Centre "Zeleznicar"-Skopje

No.	PUBLIC HEALTHCARE INSTITUTIONS - HEALTH STATIONS
1.	Health Station of the University "St. Cyril and Methodius"-Skopje
2.	Health Station "Zelezara"-Skopje

No.	PUBLIC HEALTHCARE INSTITUTIONS - GENERAL HOSPITALS
1.	Clinical Hospital-Bitola
2.	General Hospital-Gevgelija
3.	General Hospital-Gostivar
4.	General Hospital-Debar
5.	General Hospital-Kavadarci
6.	General Hospital-Kicevo
7.	General Hospital-Kocani
8.	General Hospital-Kumanovo
9.	General Hospital-Ohrid
10.	General Hospital-Prilep
11.	General Hospital-Struga
12.	General Hospital-Strumica
13.	General Hospital-Tetovo
14.	General Hospital-Veles
15.	General Hospital-Stip
16.	Military Hospital-Skopje

No.	PUBLIC HEALTHCARE INSTITUTIONS - SPECIALIZED HOSPITALS
1.	Specialized Hospital for Surgical Diseases "St. Naum Ohridski"-Skopje
2.	Specialized Hospital for Gynaecology and Obstetrics "Cair"-Skopje
3.	Mental Hospital "Skopje"-Skopje
4.	Mental Hospital-Demir Hisar
5.	Mental Hospital "Negorci"-Gevgelija
6.	Specialized Hospital for Children's diseases-Ohrid
7.	Specialized Hospital for Pulmonary Diseases and TBC "Jasenovo"-Veles
8.	Specialized Hospital for orthopaedics and traumatology "St. Erazmo"-Ohrid

No.	PUBLIC HEALTHCARE INSTITUTIONS - INSTITUTES FOR HEALTH PROTECTION
1.	Republic Institute for Health Protection-Skopje
2.	Institute for Health Protection-Skopje
3.	Institute for Health Protection-Bitola
4.	Institute for Health Protection-Veles
5.	Institute for Health Protection-Kocani
6.	Institute for Health Protection-Prilep
7.	Institute for Health Protection-Kumanovo
8.	Institute for Health Protection-Strumica
9.	Institute for Health Protection-Tetovo
10.	Institute for Health Protection-Stip
11.	Institute for Health Protection-Ohrd

No.	PUBLIC HEALTHCARE INSTITUTIONS - INSTITUTES
1.	Republic Institute for Transfusion-Skopje
2.	Institute for Physical Medicine and Rehabilitation-Skopje
3.	Gerontological Institute "13 Noemvri"-Skopje
4.	Institute for Prevention and Therapy of Cardiovascular Diseases-Ohrd
5.	Institute for Nephrology-Struga
6.	Institute for Rehabilitation of Hearing, Speech and Voice-Bitola
7.	Institute for Prevention, Therapy and Rehabilitation of Chronic non-specific Respiratory and Allergic diseases - Otesevo
8.	Institute for Children's Pulmonary Diseases "Kozle"-Skopje
9.	Institute for Pulmonary Diseases and TBC-Skopje
10.	Hospital for Prolonged Therapy and Rehabilitation "Katlanovska Banja"-Katlanovska Banja

No.	PRIVATE HEALTHCARE INSTITUTIONS - HOSPITALS
1.	PrHI „Mala Bogorodica-Sistina” Special Hospital for Gynaecology and Obstetrics-Skopje
2.	Cardio-Surgery „Filip II”-Skopje
3.	“REMEDIKA”-Skopje

No.	PRIVATE HEALTHCARE INSTITUTIONS - FOR ELDERLY HEALTHCARE
1.	PrHI „Humanost” Str.Vera Jovic 4-a - Skopje
2.	PrHI „Meri Terzieva” Str.Vladimir Komarov bb - Skopje
3.	PrHI „Panada” v.Oresani - Skopje
4.	PrHI „Zana-S” Str.8 No.15 - Skopje
5.	PrHI „Majka Tereza” Str.4-ti juli bb Zlokukjani - Skopje

No.	PRIVATE HEALTHCARE INSTITUTIONS - LABORATORIES
1.	„Dijagnostika PHARMACHEM“ Str.4-ti juli No.2/3 - Skopje
2.	„Dijagnostika PHARMACHEM“ Blvd.Jane Sandanski No.65 - Skopje
3.	„AVICENNA“ Str.Vodnjanska bb - Skopje
4.	”ADRIA LAB” – Skopje
5.	”ANALYSIS” Str.Vodnjanska bb - Skopje
6.	”Kuzmani i Damjan” Str.Lavcanski pat bb - Bitola
7.	Diagnostic Centre “Sv. Spas” v.Kravari-Bitola

Total number of HIs: 100

ANNEX III

**Calculated HC waste generated amounts at Hospitals and Specialised
Institutes, and methodology used for calculations**

Table III 1. Calculated HC waste generated amounts at Hospitals and Specialised Institutes

Hospitals and Specialised Institutes	Group	Number of beds	Patient days per year	HCRW kg/year	Ordinary waste kg/year	HCRW kg/bed-day	HCRW kg/patient day	Ordinary waste kg/bed-day	Ordinary waste kg/patient day
Clinical Centre - Skopje	1	1.855	495.640	159.721	442.500	0,24	0,32	0,65	0,89
General Hospital - Kumanovo	1	350	59.787	11.540	257.400	0,09	0,19	2,01	4,31
General Hospital - Tetovo	1	443	92.808	N/A	492.000	N/A	N/A	3,04	5,30
Clinical Hospital - Bitola	1	657	110.926	N/A	N/A	N/A	N/A	N/A	N/A
General Hospital - Stip	1	500	111.593	12.960	432.000	0,07	0,12	2,37	3,87
General Hospital - Kocani	1	160	27.671	N/A	130.000	N/A	N/A	2,23	4,70
General Hospital - Struga	1	99	25.088	8.395	15.695	0,23	0,33	0,43	0,63
General Hospital - Ohrid	1	256	56.200	24.200	157.500	0,26	0,43	1,69	2,80
General Hospital - Gevgelija	1	144	25.660	N/A	N/A	N/A	N/A	N/A	N/A
Private Hospital - "Sistina"	1	27	6.066	1.600	N/A	0,16	0,26	N/A	N/A
Private Hospital - "Filip II"	1	29	8.462	3.702	10.000	0,35	0,44	0,94	1,18
Inst. Pul. Di.& Tub. - Skopje	2	100	22.000	350	1.770	0,01	0,02	0,05	0,08
Inst. Gerontol. 13 Nov. - Skopje	2	275	97.030	704	5.940	0,01	0,01	0,06	0,06
Spec. Hospital "Cair" - Skopje	1	138	19.602	7.390	94.500	0,15	0,38	1,88	4,82
Clinic Maxillofacial sur. - Skopje	1	35	6.000	3.746	7.300	0,29	0,62	0,57	1,22
Inst. CVD - Ohrid	2	100	22.900	592	21.900	0,02	0,03	0,60	0,96
Spec. Hos. "St. Erazmo" - Ohrid	2	300	50.000	5.000	50.000	0,05	0,10	0,46	1,00
Psych. hos. - Demir Hisar	2	445	150.220	720	143.000	0,0044	0,0048	0,88	0,95
Psych. hos. "Negorci" - Gevgel.	2	210	72.721	N/A	77.500	N/A	N/A	1,01	1,07
Inst. Rehabilitation - Otesevo	2	72	12.700	N/A	14.300	N/A	N/A	0,54	1,13
Spec. Hos. "Jasenovo" - Jeles	2	100	16.973	N/A	N/A	N/A	N/A	N/A	N/A
In total		6.295	1.490.047						
					<i>Average values (Group 1)</i>	<i>0,20</i>	<i>0,34</i>	<i>1,29</i>	<i>2,32</i>
					<i>Average values (Group 2)</i>	<i>0,02</i>	<i>0,03</i>		

Source: Questionnaire survey, January 2007

Regarding generated HCW amounts the figures fall into two distinctive groups; Group 1 comprising hospitals etc. conducting "traditional" treatment and therapy where this kind of waste is generated in bigger amounts, and Group 2 where the treatment typically only will generate small amounts, like for instance in mental hospitals, rehabilitation healthcare facilities, etc.

An average value for HCW generation of 0.2 kg/bed-day for hospitals and specialised institutes performing secondary and tertiary healthcare services in the Republic of Former Yugoslav Republic of Macedonia was used. This figure was based on measured quantities at the "Drisla" landfill for the area of Skopje and Kumanovo. However, only for establishments in Skopje the figure of 0.24 kg/bed was used, based on actual measured amounts at the "Drisla" gate. The daily estimated quantities were multiplied by the number of beds for each hospital.

An average of 0.34 kg/patient/day were used for the first group and 0.03 for the second group respectively. This figure was multiplied by reported number of treated patients in the year of 2006.

ANNEX IV

Number of hospital beds in different categories of HIs

Table A IV.1. Number of beds in HIs at secondary level in the Republic of Former Yugoslav Republic of Macedonia in 2005

Health regions	General Hospitals	Specialized hospitals for mental diseases	Specialized hospitals for pulmonary diseases and TBC	Centres for treatment and rehabilitation	Other specialized hospitals	Private hospitals	Total number of beds
R. Former Yugoslav Republic of Macedonia	4086	1176	358	837	933	562	7952
Bitola	631	-	-	-	-	-	631
Veles	309	-	100 ¹	-	-	-	409
Gevgelija	152	242	-	-	-	-	394
Gostivar	210	-	-	-	-	-	210
Debar	70	-	-	-	-	-	70
D. Hisar	-	445	-	-	-	-	445
Kavadarci	119	-	-	-	-	-	119
Kicevo	123	-	-	-	-	-	123
Kocani	148	-	-	-	-	-	148
Kr. Palanka	28 ⁸	-	-	-	-	-	28
Kumanovo	344	-	-	-	-	-	344
Ohrid	223	-	-	220 ²	270 ⁶	-	713
Prilep	418	-	-	-	-	-	418
Resen	-	-	-	72 ³	-	-	72
Skopje	-	489	258	425 ⁴	663 ⁷	562 ⁹	2397
Struga	80	-	-	120 ⁵	-	-	200
Strumica	297	-	-	-	-	-	297
Tetovo	417	-	-	-	-	-	417
Stip	517	-	-	-	-	-	517

Source: Health Map of the Republic of Former Yugoslav Republic of Macedonia. Republic Institute for Health Protection, Skopje, 2007

Note: ¹ Specialized hospital for pulmonary diseases and TBC-Jasenovo, ² Stationary HI for treatment of children with rheumatic and other diseases-120 + Institute for prevention and treatment of cardiovascular diseases-100, ³ Institute for prevention, treatment and rehabilitation of chronic respiratory and specific diseases-Otesevo, ⁴Centre for hearing, speech and voice-Skopje, Institute for medical rehabilitation-Skopje, Hospital for prolonged Therapy and Rehabilitation "Katlanovska Banja" - Skopje ⁵Institute for dialysis, nephrology and rehabilitation-Struga, ⁶Specialized hospital for orthopaedics and traumatology-Ohrid, ⁷ Hospital for gynaecology and obstetrics-Cair-Skopje, Clinic for surgical diseases "St. Naum Ohridski"-Skopje, Institute for elderly-Skopje, ⁸In the Health Centre, ⁹ Private hospital for gynaecology and obstetrics "Mala Bogorodica" – Skopje (27), Private hospital for cardio surgery "Filip II" – Skopje (29), Private hospital "Remedika" – Skopje (56), Military Hospital – Skopje (450)

Table A IV.2. Number of beds in HIs at tertiary level in the Republic of Former Yugoslav Republic of Macedonia in 2005

Total (1 + 2 + 3 + 4)	2033
1. Clinical Centre, Skopje - Intrinsic group	998
Clinic for infectious diseases and febrile conditions-Skopje	129
Clinic for children's diseases-Skopje	240
Clinic for neurology	101
Clinic for mental diseases	59
Clinic for skin and sexual transmitted diseases	61
Clinic for gastroenterohepatothology	55
Clinic for pulmonary and allergic diseases	46
Clinic for cardiology	120
Clinic for toxicology	34
Clinic for nephrology	41
Clinic for endocrinology	35
Clinic for rheumatology	42
Clinic for haematology	35
2. Clinical Centre, Skopje - Surgical group	857
Clinic for surgery	357
Clinic for orthopaedics	100
Clinic for gynaecology	164
Clinic for obstetrics	62
Clinic for ear, nose and throat	95
Clinic for eye diseases	79
3. Institute for radiotherapy and oncology	135
4. Clinic for maxillofacial surgery-Skopje	43

Source: Health Map of the Republic of Former Yugoslav Republic of Macedonia. Republic Institute for Health Protection, Skopje, 2007

Table A IV.3. Private Health Institutions in the Republic of Former Yugoslav Republic of Macedonia in 2005

Health regions	Dentist ambulatories		Pharmacies		Laboratories	
	City	Rural	City	Rural	City	Rural
R. Former Yugoslav Republic of Macedonia	660	85	438	60	52	2
Berovo	7	-	9	-	1	-
Bitola	32	7	35	-	2	-
M. Brod	3	1	1	1	-	-
Valandovo	6	-	3	-	-	-
Veles	24	5	14	2	3	-
Vinica	6	1	4	-	-	-
Gevgelija	5	7	7	6	1	-
Gostivar	36	9	15	7	3	-
Debar	4	-	3	-	-	-
Delcevo	5	1	6	-	1	-
D. Hisar	4	-	3	-	-	-
Kavadarci	23	-	14	-	2	-
Kicevo	9	1	8	-	-	-
Kocani	18	4	7	-	-	-
Kratovo	2	-	2	-	-	-
Kr. Palanka	5	-	2	-	-	-
Krusevo	2	-	2	-	-	-
Kumanovo	38	2	35	2	5	-
Negotino	6	2	4	2	2	-
Ohrid	20	1	18	-	1	-
Prilep	36	8	24	2	-	-
Probistip	-	-	2	-	1	-
Radovis	8	-	8	-	2	-
Resen	9	1	4	-	-	-
Sv. Nikole	5	1	3	1	-	-
Skopje	237	10	130	30	14	-
Struga	13	4	13	1	-	-
Strumica	39	11	24	4	5	-
Tetovo	42	9	28	2	6	2
Stip	16	-	13	-	3	-

Source: Health Map of the Republic of Former Yugoslav Republic of Macedonia. Republic Institute for Health Protection, Skopje, 2007

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