



## Hamadan University of Medical Sciences

Title: Rules and methods of executive management of medical residues and related residues

Text: Number: 15871/T38459K

Ministry of Health, Treatment and Medical Education

Environmental Protection Organization

Infrastructure Affairs Commission

Industry and environment

In the meeting dated 19/12/1386 according to the proposal No. 39169-1, dated ۲۰۰۷, September, 23 of the Environmental Protection Organization

Based on Article (11) of the Waste Management Law - approved in ۲۰۰۴

In accordance with part (3) of paragraph (c) of the Resolution No. 56061/1901 dated 2004, July, 15 of the Supreme Administrative Council,

It approved the rules and methods of executive management of medical waste and related waste as follows:

Rules and methods of executive management of medical waste and related residues.

Chapter one - goals

Article 1 - The implementation of these rules aims to achieve the following goals:

A- Protecting public health and the environment against the adverse effects of medical waste.

B- Ensuring proper and regulated executive management of medical waste.

C- Creating appropriate and regulated procedures for the production, transportation, storage, treatment, destruction and disposal of medical residues.

#### Chapter tow - definitions

Article 2- The following phrases and terms used in their respective meanings:

A- Law on waste management: It means the law on waste management - approved in 2004.

B- Organization: Environmental Protection Organization.

C- Ministry: Ministry of Health, Treatment and Medical Education

D- Special medical residues :Is said to all infectious and harmful residues from hospitals, health care centers, medical diagnosis laboratories, and other similar centers which, due to the high level of at least one of the dangerous properties such as toxicity, pathogenicity, explosion or ignition, Corrosive or similar that need special care (special management).

E- The four main categories of medical waste:

1- Infectious residues

2- Sharp and sharp residue

3- Chemical and pharmaceutical residue

4- Normal residue.

F- Decontamination: measures that remove the dangerous characteristic of medical residue.

G- Other definitions contained in these rules will be the same as the definitions of the law and executive regulations of residues management.

#### Chapter 3 - scope of authority

Article 3- The Ministry is responsible for supervising the implementation of approved rules and procedures.

Article 4- The implementation of the approved rules and methods is mandatory for all real and legal persons who produce, segregate, separate, collect, receive, store, transport, purify, dispose or manage medical waste in any form.

Article 5 \_ Executive managements of residues are obliged to adopt an arrangement based on the criteria and regulations of the Ministry to provide and guarantee the health, hygiene and safety of executive agents under their supervision.

Article 6 - Residues producers are required to have an operational plan in order to reduce the amount of waste production.

Article 7- All real and legal persons who intend to establish a medical center, including hospitals, clinics, and clinics, are required to submit the executive waste management plan of the said unit to the approval of the Ministry.

Article 8-\_ Special medical waste, based on the definition in the law, considered as special waste until the time it turns into normal residue.

Chapter 4 - Classification of medical residues Article 9 - The classification of medical residues is as follows:

A- Normal (quasi-domestic)

B- Residues from medical care (special medical residues)

In the attached table, Number (1), which approved by the seal of "Appendix of the Cabinet of Ministers' approval letter", a detailed description list of these wastes presented.

Chapter five-\_ separation, packaging and collection

Article 10- All centers that produce medical waste (including hospitals, clinics, health centers, laboratories, injection centers, radiology centers, dentists, physiotherapists, practices and other medical waste production centers) are obliged to dispose of normal residue and residue at the source of production, collect, separate and pack their special medical residues according to the following points:

Article 11- In order to manage residues fine, medical residues producing centers (including hospitals, clinics, health centers, laboratories, injection centers, radiology, dentists, Physiotherapies, clinics and other medical residues production centers) are required to perform the following measures:

A- The preference is to use products with less and non-hazardous residues generation (in the case of normal (quasi-domestic) hospital residues, products with recyclable residues production).

B- Appropriate management and supervision of consumption.

C- Accurate separation of normal residue from special medicine at the origin of waste production.

D- Preferring to use less dangerous products instead of PVC,

E-Using less dangerous colors instead of colors with a metal base.

F- The priority of using:

1- Biodegradable cleaners.

2- Safer chemicals.

3- Using water-based materials instead of solvent-based materials.

Article 12- Each unit must draw up its own special medical residue management operational plan and submit it if requested by the representatives of the organization or the ministry.

Article 13- Producers of medical waste are obliged to identify their production residue and record the production statistics on a daily basis by separating "infectious", "sharp ", "chemical-medicinal" and "normal".

Article 14- Producers must dispose of special medical residue in order to ensure safe transportation.

Reducing the volume of medical residue, especially

Reduction of waste management costs

Correcting and ensuring erasure,

Separate from normal waste process.

Note - It is necessary to separate different types of medical waste into four main categories.

Article 15- not all residues that have the same disposal method need to separate from each other.

Article 16- The residues containing dangerous heavy metals must separate separately.

Article 17- If the normal residues mixed with one of the infectious, chemical, radioactive and similar residues, it prohibited to take out them.

Article 18- Immediately after production, medical residues must place in bags, containers, or containers that meet the conditions listed in this section.

Note - If the autoclave method used for residue treatment, it is necessary that the plastic bag of infectious waste and the Safety Box can be autoclaved.

Article 19- The packaging of special medical waste should done in such a way that it does not have the possibility of any leakage, hole or tear.

Note - Since packages containing residue usually occupy a large volume, these packages should not compressed before treatment or disposal.

Article 20 - The severed body parts and parts of the dead fetus collected and separated according to religious rules.

Article 21 - Segregated waste must be stored in containers and bags as described in Table No. (1) Of Appendix No. (3), which has approved by the "Appendix of the Board of Ministers" seal.

Article 22- All sharp residues must be collected and stored in safety boxes, which must have the following characteristics:

A- Do not pierce or tear easily.

B- It can easily closed and sealed.

The size of the container should be large enough to put the waste in the container without applying hand pressure and it is not possible to remove it from the container.

C- The edges of the container should be impenetrable and liquids cannot escape from it.

D- After closing the lid of the container, make sure that the material does not come out.

E- The container should be easy and convenient to transport.

Article 23- Do not use plastic bags to collect and store sharp residues.

Article 24- Condensing, compressing and shredding device should not use for medical waste unless disinfection or decontamination of the waste has been done before or at the same time as using the above device.

Containers for collecting sharp and cutting residue should not be compacted by any device.

Article 25- Plastic bags must at least have the following characteristics:

A- To use for collecting and storing waste other than sharp waste.

B- Do not fill more than two-thirds of the capacity so that the doors can closed well.

C-Do not close with staples or other piercing methods.

Article 26- Containers with hard edges must at least have the following characteristics:

A- To be resistant to leakage, ordinary blows, breakage and corrosion

B- It should checked and controlled after each use to ensure that it is clean, healthy and does not leak.

C. Defective containers should not reused.

Article 27- Liquids, blood products and body fluids should not be poured and transported in plastic bags unless they are in special containers or bags.

Article 28- The material of residue storage containers must be compatible with the purification or disposal method, and plastic containers must be made of halogen-free plastics.

Article 29 - Cytotoxic residues must be stored in tight and leak-proof containers.

Article 30- After collecting the medical residues in the containers and bags described in Table No (1) Of Appendix No (3), which has approved by the seal of "Appendix of the Board of Ministers' approval letter", for storage and transportation, inside a bucket with Specific colors should place. If these buckets are reusable, they should washed and disinfected after each emptying.

Note - The following methods used to remove contamination and disinfection from buckets:

A- Washing with hot water at least 82 degrees Celsius (180 degrees Fahrenheit) for at least 15 seconds.

B- Disinfection with the following chemicals for at least three minutes:

1- 500 ppm chlorine hypochlorite solution available.

- 2- Phenol solution 500-ppm active agent.
- 3- 100 ppm iodine solution available.
- 4- Quaternary ammonium solution 400 ppm - active agent.
- 5- Other disinfectants with a medium spectrum license.

Article 31 - Inclined surfaces should not be used to transfer and move infectious waste

Article 32- The Institute of Standard and Industrial Research of Iran is obliged, with the cooperation of the Ministry and other executive agencies, as the case may be, to implement the standards of Article (3) of the Law and Article (16) of the Executive Regulations of the Waste Management Law related to medical waste within three months.

Article 33- Labeling must have the following features:

A- No bag-containing residue should leave the production site without having a label and specifying the type of bag content.

B- Bags or containers containing waste must be labeled.

C- Labels with a readable font should be pasted on the container or bag or printed.

D- The label should not be easily removed or erased due to contact or transportation.

E- The label must be visible from all sides.

G- The hazard symbol specifying the type of waste should be in the form listed in Table No. (2) Of Appendix No. (3), which is approved by the seal of "Appendix of the Board of Ministers" for infectious waste, radioactive waste, and cytotoxic residue.

H- The following information should be mentioned on the label:

- 1- Name, address and contact number of the manufacturer.
- 2- Type of residue.
- 3- Date of production and collection.
- 4- Delivery date.
- 5- Type of chemical substance.
- 6- The date of decontamination

Article 34- Waste transportation officials are obliged to refrain from receiving waste without labels.

Article 35- When three quarters of containers and bags containing special medical residue are full, they must be collected after closing.

Article 36- Infectious and ordinary residues must be collected every day (or several times a day if necessary) and transported to the designated place for temporary waste storage.

Article 37- Used bags and containers must be replaced with bags and containers of the same type immediately.

Article 38- Garbage bins should be washed and disinfected immediately after removing the bag filled with residue.

## Chapter Six \_ Storage

Article 39- Storage of medical residue should be done separately from other normal waste.

Article 40- The place of temporary accumulation and storage must be designed inside the waste production center.

Article 41- The residue storage site must have the following conditions:

A- Medical residues should be stored in a place away from the influence of atmospheric factors and the general condition of their packaging or container should be protected against adverse weather conditions such as rain, snow, heat, sunlight and the like.

B- Residue storage places should be built in such a way that it is impervious to moisture and provides easy storage with proper sanitary conditions.

C- The storage places should be far away from the service area of the employees, the kitchen, the washing and cooling system, and the place of departure and arrival of the personnel, patients and clients.

D- The storage places should be far away from the service area of the employees, kitchen, air-conditioning, refrigerating and the place of movement of the personnel, patients and clients.

E- The entry and exit of insects, rodents, birds and the waste storage area would not be possible.

G- The residue storage area must have a clear sign.

H- The storage place should not provide the possibility of spoilage, contamination or biodegradation of residues.

I- The storage of this residue should not be done in such a way that containers or bags are torn and their contents left in the environment.

J- It should be possible to control the temperature in the storage warehouse and there should be enough light.

K- There should be a proper ventilation system with output control. Its ventilation system should be controlled and there should be no natural airflow from it to the adjacent parts.

L- Cleaning and disinfecting the place and decontamination is possible.

M- Sufficient space should be available to prevent the overlapping of residue.

N- It should have a solid roof and a suitable sewage system.

O- The access and transportation of residue should be easy.

P- Loading with trucks, vans and other cargo vehicles is possible.

Q- The warehouse should have proper security.

R. The place should be equipped with hot and cold water and floor washing system.

S- Since decontamination done in the production storage room, there should be enough space to install the desired systems in the waste storage area.

Article 42- The storage place for small units can include bins with a security system located in a safe place.

Article 43- The residue storage place must have a suitable and reliable security system, the entry and exit of waste must supervised by the relevant responsible person and the entry of irresponsible persons must prevented. (Locking be possible).

Article 44- The manufacturer should visit the place in order to prevent leakage or infection.

Article 45- In the absence of a cooling system, the temporary storage time (time interval between production and purification or destruction) should not exceed the following:

A- Moderate weather conditions: 72 hours in the cold season and 48 hours in the hot season.

B- Hot weather conditions: 48 hours in the cold season and 24 hours in the hot season.

Article 46- Types of special medical residue must be stored separately from each other and the storage location of each type of waste must be marked with a characteristic sign. In particular, infectious, cytotoxic, chemical, and radioactive waste should not exposed to each other in any way.

## Chapter Seven \_ Transportation

Article 47- Transportation in the residue-producing unit should carried out as follows:

A- Waste transportation inside the residue production center should designed in such a way that it is possible to use a hand wheel or a cart for easy loading and unloading of residue.

B- It should not have sharp and cutting edges, so that it does not tear the bag or dishes.

C- It should be easy to wash.

D- Equipment should cleaned and disinfected every day.

E- Do not use the residue wheelbarrow to carry other materials and should not leak.

F- Don't use the throwing system to transfer residue to the storage place.

Article 48- It is necessary to replace the conveyance of transporting residue from the end of the ward in the hospital to the temporary storage place.



Article 49- In units where the volume of residue production is small, such as polyclinic, washable, non-leaking, resistant trash cans can used, as well as resistant bags for carrying residue.

Article 50 - The residue producer can entrust the transportation of residue to the disposal site through a contract to competent companies, monitoring the good performance of the work will be the responsibility of the producer in accordance with Article (7) of the Residue Management Law.

Article 51 - Moving, transporting, and loading packages and containers should done in such a way that the state of the packages and containers remain stable and do not leak, tear, break, or spill residue.

Article 51 - Moving, transporting, and loading packages and containers should done in such a way that the state of the packages and containers remain stable and do not suffer from leakage, tearing, breakage, and spillage.

Article 52 - The transboundary transportation of residue is subject to the rules and regulations of the Basel Convention.

Article 53 - Loading must done under the following conditions:

A- The disposal unit should strictly refrain from receiving unlabeled residue.

B- The workers must properly covered during the various stages of loading and unloading according to the guidelines of Article (5) of the Residue Management Law compiled by the Board of Ministers and as described in Appendix No(4) Which approved by the "Appendix of the Cabinet of Ministers" seal.

C- Bags and containers can placed directly in the car.

Article 54 - The vehicle-carrying residue must have the following features:

A- Be completely covered.

B- The part of the cargo should be impermeable and leak-proof.

D- The cargo area should be double-glazed or double-shelled and have a system for collecting and storing the leachate.

E- The cargo area should have a safety, fire and anti-theft system.

F- The international symbol of the type of waste, the name of the transport company and the license number of the vehicle should written on the body of the car on both sides and on the backside.

G- Don't use the garbage truck to transport other materials or normal residue.

H-The size of the car should be proportional to the amount of residue.

I- The internal height of the car should be about 2.2 meters.

J- The driver's cab should be separate from the cargo area.

K- Cleaning and disinfecting be possible. The floor of the car should not made of carpet or moquette, and if possible, it should have a uniform covering without chink.

L- The cargo area should be locked during transportation and when not in use.

Article 55 - Cars whose cargo area can separated are preferable, in this way, the cargo area can placed in the loading unit or used as storage and after being filled, it can be replaced with an empty truck or other suitable vehicles.

Article 56 - In cases where the storage or transportation time is longer than the times mentioned in Article (46), trucks with a cooling system should use.

Article 57 - Low-traffic and low-accident routes should use to deliver residues to the disposal site.

Article 58 - Transportation of medical waste only by competent companies and based on permission

There should be forms issued by the ministry and the organization, and if necessary or requested, they should submitted to the supervisory authorities, including the Ministry, the Organization, and the traffic polices.

Note - The transportation of medical residue by post prohibited.

Article 59 - Residue should transported only to the final destination specified in the permit, without wasting time.

Article 60 – Moving and transporting segregated special medical residues with normal residues, prohibited.

## Chapter eight \_ Decontamination, purification and destruction

Article 61 - The selection of the method of decontamination and disposal of special medical residue depends on various factors, including the type of residue, the efficiency of the disinfection method, environmental and health considerations, climatic conditions, population conditions, the amount of residue and the like.

Article 62 - Each producer of special medical residue must choose one or a combination of decontamination, purification and disposal methods and implement them after the approval of the Ministry.

Article 63 - The location of the system used in the case of centralized systems must approved by the organization in terms of technical and pollutant output.

Article 64 - Decontamination of infectious and sharp residue by major centers that produce special medical residue (such as hospitals) and in medium or large cities should be done at the place of production in order to minimize the risks caused by transportation or related costs. In small cities, villages and small centers, residue can be stored safely in a central site.

Article 65 - Other special medical residue production centers (including clinics, health centers, Laboratories, injection centers, radiology, dentistry, physiotherapies, clinics, and other medical residue production centers) can safely dispose of produced waste at a regional or central site or use the facilities of nearby hospitals.

Article 66 - Delivery of residue to unlicensed central treatment or disposal units prohibited.

Article 67 - Centralized non-hazardous waste units must receive permission from the Ministry and Organization.

Article 68 - According to Article (7) of the Management Law, after converting special medical waste into normal residue, its management mechanism is the same as normal residue.

Article 69 - Every method of converting special medical residue into normal should have the following characteristics:

A- The device must have the ability of microbial inactivation of bacterial spores (Microbial efficacy inactivation) to the extent of at least (6) logarithmic reduction in the base (10). (Log 610)

B- Toxic or dangerous side products should not produce during decontamination.

C- To eliminate the risk and possibility of transmission of disease and infection.

D- There should be documentation related to the process and checking the correctness of the device's operation.

E- The output of each method should be safe for humans and the environment, and it should be easily disposed of without any other process.

F- In terms of safety, it has suitable conditions and the safety of the system maintained in all stages of the work.

G- Be economical.

H- To be acceptable by the society.

I- in terms of health and safety, to be safe for employees, customers, etc. in terms of health and safety, or it creates minimal risk.

J- Be in line with the country's international commitments.

K- All the methods used must approved by competent authorities in the form of waste management.

L- In epidemic and special times, the Ministry announces a new and temporary standard in accordance with the conditions and at least up to (6) logarithmic reduction based on (10) indicator bacteria.

M- The severed organs and limbs should collected separately and transported to the local cemetery for disposal, as well as disposed of in their own way.

Note - The rules and criteria of the main methods of purification will found in the appendix number (2) which approved by the seal of "Appendix of the Board of Ministers".

Article 70- in cities it i prohibited to install any type of waste incinerator, whether centralized or decentralized.

Article 71- The establishment of any central purification or disposal system will be subject to environmental impact assessment studies.

Article 72- With the change of technology and the introduction of new technologies, the production units are obliged to check the efficiency of these technologies and if confirmed, they will used instead of older methods.

Article 73- These regulations considered as replacement regulations for any previous regulations in this regard, and if there are similar cases, these regulations are valid and enforceable.

Parviz Davodi - First Vice President

Title: Appendices of regulations and methods of executive management of medical residue and related residue.

Text: Attachment 1

Classification table of special medical residue:

Description of types of special medical residue:

1- Infectious waste:

Infectious wastes suspected of having living pathogenic agents (bacteria, viruses, parasites or fungi) in quantity and quality that can cause disease in sensitive hosts.

This category includes the following:

Cultivation of pathogenic agents and stored materials resulting from laboratory work, wastes resulting from surgical operations and autopsies of corpses with infectious diseases (such as tissues, materials and equipment that were in contact with blood or other blood fluids and secretions of the body).

Residues of infectious patients hospitalized in the isolation ward (1) (such as excrement, surgical or infectious wound dressings, clothes contaminated with human blood or other bodily fluids and secretions),

Residues from infectious patients hospitalized in the isolation ward (1) (such as excrement, surgical or infectious wound dressings, clothes contaminated with human blood or other body fluids and blood secretions), wastes that have been in contact with infectious patients and hemodialyzed (such as dialysis equipment, including Tubing and filters, disposable towels, gowns, aprons, gloves and laboratory clothes), contaminated laboratory animals.

Any type of tools or other materials that have been in contact with people or animals that have contaminated.

Note: Contaminated "sharp objects" are also a sub-category of infectious waste, but they described separately in these criteria.

Highly polluting wastes are:

Cultivation and stored materials are highly polluting and contain infectious disease agents, residues of autopsies, animal corpses, other residues that have been inoculated or infected with them, and have been in contact with such disease agents.

## 2- Traumatic residuals

Pathological residuals include

Tissues, organs, body parts, human embryos, animal corpses, blood, fluids and blood secretions are the body. In this category, identifiable parts of human and animal bodies called "anatomical residues".

## 3- Sharp objects

Sharp objects are items that can cause wounds such as cuts or punctures, which include: needles, hypodermic needles, surgical knife blades and other blades, knives, infusion heads, saws, broken glass, and nails of patients and ... which may or may not be infectious, which are still considered as highly threatening health residues.

## 4- Pharmaceutical waste

Pharmaceutical residues includes expired, unused, separated and contaminated drugs, vaccines, drugs and serums that no longer needed and should be disposed of properly.

This category also includes discarded items used in pharmaceutical work, such as bottles, cans with dangerous drug residues, gloves, masks, connecting pipes, and glass (vials) of drugs, which, if released into the environment, can be harmful to humans and the environment.

## 5- Genotoxic residue:

Genotoxic residues are extremely dangerous which cause serious safety and health problems, including causing cell mutation, causing the birth of strange creatures (human but not human) and carcinogenicity.

These problems can be both inside the hospital and after residue disposal outside the hospital, which should give special attention.

Genotoxic residues can contain specific cytotoxic drugs (as described below), cytotoxic, chemical substances and radioactive substances.

Cytotoxic (or anti-neoplastic) drugs, which are the main ingredients of this category, can kill some living cells or stop their growth.

These drugs used for the chemotherapy of cancers.

Cytotoxic drugs play an important role in the treatment of various neoplastic diseases. They are also widely used as immunosuppressive agents during organ transplantation and the treatment of various immunologically based diseases.

Cytotoxic drugs often used in specialized departments such as oncology and radiation treatment units, whose main role is to treat cancer.

The most common genotoxic substances used in health care shown in the box below.

Dangerous cytotoxic drugs can be classified as follows:

The most common genotoxic products used in healthcare and treatment

1- Chemicals classified as carcinogens:

Benzene

Cytotoxic drugs, etc.

Azathioprine, chlorambucil, chlorambucil, cyclosporine, cyclophosphamide, melphalan, simustine, tamoxifen, thiotepa, tresulfan, radioactive substances

2- Classified as a possible or probable carcinogen

Cytotoxic substances and other drugs:

Azacytidine, bleomycin, carmustine, chloramphenicol, chlorzotocin, cisplatin, dacarbazine, doxorubicin, dihydroxymethylfluoratriazine (such as panfuran, which is no longer used), doxorubicin, lomustine, methylthiouracil, metronidazole, mitomycin, nifedipine, niridazole, oxazepam, Phenastine, phenobarbital, phenytoin, procarbazine hydrochloride, progesterone, sarcolysin, streptozocin, trichlormethine.

3- These classifications are according to the classification of the working group of the International Organization for Research on Cancer.

(IARC) Alkylating substances: which cause alkylation of DNA nucleotides, and lead to cross-linking and wrong coding in the gene pool.

Antimetabolites: which have an inhibitory effect on the nucleic acid biosynthesis of the cell.

Cytotoxic residues generated from several sources in health care and they can be categorized as follows:

Materials contaminated with pharmaceutical products and prescription drugs such as syringes, needles, vials, packaging, expired drugs, and drugs returned from hospital departments.

In specialized cancer hospitals, genotoxic residues (containing cytotoxic or radioactive substances) may constitute 1% of the total medical residues.

6- Chemical waste

Chemical residues include solid materials and chemical gases that used for diagnosis or experiments, cleaning, housekeeping and disinfection.

Chemical residues of health care can be dangerous or harmless.

These residues considered dangerous in terms of health protection if they have at least one of the following characteristics:

Toxic;

- Corrosive properties (such as acids with  $\text{pH} > 2$  and bases with  $\text{pH} < 12$ ); Spontaneous combustion capability;

- Flammable reaction (such as explosive materials, materials that react with water, and are sensitive to impact);

Genotoxic (such as cytotoxic drugs)

Non-hazardous chemical residues includes those chemical substances that do not have any of the above-mentioned characteristics, such as compounds, amino acids, and some organic and inorganic solvents.

The types of dangerous chemicals commonly used in healthcare facilities and hospitals, which are most likely to find in residues, described in the following paragraphs:

#### 7- Residues containing heavy metals

Residues containing heavy metals are a subcategory of hazardous chemical residues, and are usually highly toxic.

Mercury-containing residues typically result from the leakage of broken clinical equipment

The mercury emitted from such devices should collected as much as possible.

The remains of dental works also contain a large amount of mercury.

Cadmium-containing residues mainly come from discarded and broken batteries.

Wood-reinforced panels with some lead still used as X-ray shields and in diagnostic departments.

Some types of drugs have arsenic, but in these criteria, they described as pharmaceutical residues.

#### 8- Pressured vessels

Many types of gases used in health care or in laboratory equipment (see box below).

These gases are mostly in pressurized cylinders, spray cans, many of them can be used again when they are empty or can no longer be used (while there is still some gas left in them), but some other types - especially spray cans - should be disposed of properly.