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Sterilization of infective health care waste in hospitals

Manzi Pietro [1], Di Maria Francesco [2], Di Fant Marcella[3]

Affiliation
[1]Direttore Sanitario Azienda Ospedaliera di Terni
[2]Dipartimento di Ingegneria – Università degli Studi di Perugia
[3]Azienda Sanitaria Universitaria Friuli Centrale

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ABSTRACT

Collection and disposal of infective medical waste represents a well-known problem in all Italian and foreign hospitals.

Pandemic events have increased the attention and sensitivity on the topic both from a legal/regulatory and technical-professional perspective.

latest legislation introduced some noticeable modification in the perception of the problem changing the particularly precautionary approach largely exploited in the past, putting the sterilization procedures at the center of a more efficient management of such waste materials. Contemporary the specific industrial sector is developing and proposing on the market sterilization equipment able to minimizing the risk of pollution and reducing the volumes of material to be disposed of.

This article addresses the topic with particular focus on the advantages, drawback and specific aspect to be considered for the realization of an in-situ sterilization for infective hospital waste. Different aspects related to biological, environmental, financial legal and medical liability risk, which become essential for allowing a careful evaluation and conscious choice, were also considered and discussed.

INTRODUCTION

One of the main environmental and economic costs for hospitals is represented by the collection, the storing, the treatment and the disposal of health care with infective risk. From the legal point of view such waste are classified as special waste and belongs to the chapter 18 of the European Waste Catalogue (EWC) and identified by the following codes: 18 01 03*; 18 02 02*.

During the year 2021 in Italy were generated 265,134 tons of health care waste 90% of which (i.e. 238,872 tons) classified as hazardous corresponding to about 2.1% of the whole amount of hazardous waste generated in Italy (1). Of these 201,353 tons were the amount identified by the EWC 18 01 03*. Of these about 60,000 tons were recovered by recovery operations R1 “Use principally as a fuel or other means to generate energy”, R2 “Solvent reclamation/regeneration” and R12 “Exchange of waste for submission to any of the operations numbered R 1 to R 11” (Annex C, Section IV, D.Lgs. 152/06) (2).

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During the same 2021 15,000 tons were recovered by energy recovery operations R1, higher than the 11,000 tons of the previous year, whereas about 45,000 tons were processed according to R12 operation that includes also the sterilization treatment. The remaining about 187,000 tons were disposed according to the operations D8 "Biological treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any of the operations numbered D 1 to D 12", D9 "Physico-chemical treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any of the operations numbered D 1 to D 12 (e.g. evaporation, drying, calcination, etc.)", D10 "Incineration on land", D13 "Blending or mixing prior to submission to any of the operations numbered D 1 to D 12" and D14 "Repackaging prior to submission to any of the operations numbered D 1 to D 13" (Annex B, section IV, D.Lgs. 152/06) (2).

The amount of waste disposed by D10 "Incineration on land" operation in the 2021 were 108,328 tons, whereas about 60,000 tons were disposed by chemical-physical treatments that includes also the sterilization process -D9. Compared to the previous year the D10 operation increase of about 13,000 tons.

Considering the amount of waste treated by sterilization processes (D9 and R12), this resulted of 81,041 tons in the 2020 and of 92.221 tons in the 2021. Referring to the latter, 89,286 tons were the amount disposed of after being sterilized.

The number of Italian incinerations facilities, both D10 and R1 operation, authorized for the treatment of these waste results of 24 with a total allowed capacity of 272,930 for EWC 180103*. The 17 sterilizations premises nowadays in operation were authorized to the treatment of 439,000 tons/year of both EWC 180103* and 180202* even if the amount effectively treated in the 2021 resulted of 165,930 tons.

Based on the data reported above even if could be detected a rising tendency in managing infectious waste according to the most advanced legislation by an increase of the exploitation of recovery treatments, even if the amount disposed of still remain excessively high. This is also demonstrated by the under exploitation of the sterilization capacity.

By the way, it is worthy to be mentioned that the promotion of this approach aimed to maximized recovery operation also for this sector resulted quite recent. In fact, only after the COVID-19 pandemic the legislation started to promote a more efficient management of the materials of infective health care waste oriented to its recovery rather than to its disposal. All this also for enhancing the implementation of recycling and recovery activities in this sector as already largely implemented for other sectors (e.g. household, industrial etc. etc.).

Among the different techniques and technologies available today, the sterilization performed in the hospitals shows all the features for increasing the recycling and recovery of infective waste along with other management, environmental and economic advantages achievable under given conditions. The present study investigated and discussed in detail the advantages and the criticism associated to the implementation of sterilization facilities in single or associated hospitals premises.

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MATERIALS AND METHODS

a) The legal framework

In Italy, the management of health care waste was and still regulated mainly by the DPR 254/2003 (3) that is also in relation with the general legislation concerning the waste (section IV D.Lgs. 152/06) (2). In other word the rules reported in (2) can be applied to the health care waste only in those aspect not regulated by the (3). According to the legislation, health care waste are those generated in public or private premises in which medical activities are performed. These are classified as hazardous and non hazardous. Non hazardous can also be assimilated to municipal ones whereas hazardous can be infective and not infective. According to (3), there are different management pathways to be adopted based on the waste classification. Article 2 of (3) indicates that human and animal health care infective waste, identified by the EWC 180103* and 180202*, respectively, can be classified as municipal solid waste, corresponding to the EWC 200301, only after being sterilized. The same article 2 (3) defines the sterilization process as the treatment performed according to the technical note UNI 10384-1:1994 (7), by a procedure that also includes the shredding and the drying for decreasing the mass and the volume of the material arising from the process.

The article 7 of (3) reports that the sterilization facilities build in hospital has not to be authorized according to the procedure for conventional waste management plants only if the waste treated are generated exclusively by the same hospital. In this case a communication to the legal authority (i.e. region, province, metropolitan city) is necessary. According to the same art. 7, can be considered generated by the same hospital also those waste generated in decentralized health care structures but integrated for their organization and operation.

Since the health care organization is strictly linked to the regional legislation, the definition of decentralized sanitary structures integrated concerning the organization and the operation with the main one, should be a task of regional government. It is of prominence evidence that the maximum benefits could be achieved through an extensive interpretation of what reported above.

Another important aspect was also the modification of the old legislation on landfill (4) with the recent one (5) that state the prohibition, among the other, of the disposal in landfill of the waste identified by the EWC codes 180103* and 180202*. This recent novelty forces to move the infective waste to incineration and/or to sterilization treatment before landfilling. In fact, according to the article 9 of (3), after sterilization both EWC 180103* and 180202* can be classified as municipal solid waste identified by the EWC code 200301 "Mixed municipal waste" admitted for being disposed of in landfill.

According to the article 9 of (3), after the sterilization process, the waste must be collected and transported using specific single use packaging, e.g. liners. These must have a color different from the one used for other municipal and health care assimilated to municipal waste, on which must be clearly printed, by not erasable pen, the EWC 200301 together with "Sterilized Health Care Waste" and the date of the sterilization process.

The same article 9 of (3) at paragraph 4 regulates the case of sterilized health care waste not- assimilated to municipal one due to its exploitation to produce solid recovered fuel (SRF) or used in facilities that exploits such waste as a fuel or other means to generate

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energy (i.e. R1 operation). In this case such waste must be collected separately from municipal and assimilated ones by using the EWC code 191210. In any of the case above mentioned, including incineration both D10 and R1, the art. 11 of (3) reports that the gate fee must be the same one applied for municipal solid waste.

The same provision is also applied for those regions lacking of incineration or SRF production facilities in which the EWC 180103* and 180202* waste, after sterilization, are disposed of in landfill.

It is also worthy to be noted that once sterilized the infective health care waste can be admitted among those indicated in the art. 6 of (6) that is the Italian regulation for the production of end-of-waste SRF.

More recently and strongly influenced by the COVID-19 pandemic, latest legislation gives more emphasis to the concept of considering EWC 180103* and 180202* after sterilization as municipal solid waste EWC 200301. In fact, at the art. 30bis paragraph 1 of the legislation 120/2020 (8) relevant novelties were introduced represented by the fact that, after sterilization, EWC 180103* and 180202* waste assumed the legal status of municipal waste. This was definitively confirmed also by the response of the Ministry of Environment to a query put by the Tuscany Regional government (i.e. MASE.REGISTRO UFFICIALE.USCITA.0043348.06.).

In this perspective, the sterilized waste can also be subjected to the municipal waste fee (TARI) (9) that is based on the holding of premises or open areas in which urban waste can be produced. The art. 1 paragraph 527 of the legislation n.205/2017 (10) assigned to the authority for the regulation for energy, the networks and the environment (ARERA) also the role of controlling and regulating the sector of municipal waste. Among the different duties of ARERA there are also the following ones:

- Draw and update of the fee methodology for determining the cost of the integrated waste management service and of each single service provided on the basis of the efficient costs and of the principle polluter pays (Art. 1, paragraph 527, letter f) (10);
- Approval of the fee established by the local waste management authority and by the managers of the treatment facilities (Art. 1, paragraph 527, letter h) (10);
- Verifying the correct drawing of the waste management plans by the waste management authority (Art. 1, paragraph 527, letter i) (10).

Since today ARERA adopted the first and the second waste fee method for the period 2018-2021 and 2022-2025, respectively. Figure 1 reports the basic scheme of the different unit costs (i.e. collection, transport, treatment, recovery and disposal) used for the determination of the total waste management fee.

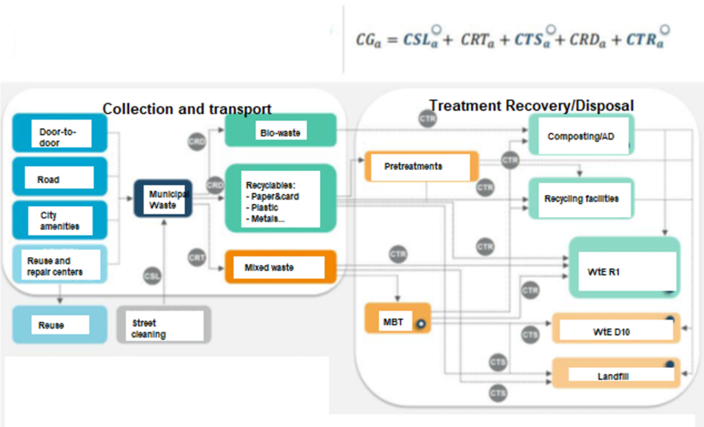

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***Figure 1**. Scheme of the urban waste management activities reporting each unit cost. (CRD = cost for sorted waste; CRT = cost for unsorted waste; CSL = costs for road cleaning; CTR = cost for treatment and recovery; CTS = cost for treatment and disposal).*

The TARI is composed by fixed and variable costs. Fixed costs are those necessary for compensating the costs of the service. Variable costs are those based on the amount of waste managed established on the surface generating the waste and on a waste production coefficient.

For this reason, the realization of a sterilization facility could lead to an increase of the surface generating municipal waste with possible increase of the whole variable costs. In the case to such surface was not already applied the TARI, this could lead to an increase of the total waste management fee. In the case the TARI was already applied, an increase in the whole fee could be caused by the application of the pay-as-you-throw fee, based on the effective amount of waste generated and hence managed. A TARI reduction can be applied by some municipalities based on the amount of waste that the producer moved to recycling (Art. 1 paragraph 649) (10). This can have effects on the only variable costs. By the way the article 238 paragraph 10 of (2) provides that, if the producer demonstrate that the waste were effectively recovered, a total cancellation of the variable costs. This can be applied to sterilized waste only if the whole waste assimilated to municipal generated by the hospital are effectively recovered.

According to the art. 1 paragraphs 667 and 668 (11) and to (12) the municipalities must replace the TARI with t pay-as-you-throw fee (TARIP or TARIC). Currently, the TARIP/ TARIC resulted implemented to only 1,298 of Italian municipalities, out of 8.833, covering about 15.2 % of the total population (1). A full implementation of such fee can lead to more complex assessment of the effective benefits achievable by hospitals for the assimilation of health care waste to municipal ones.

b) The collection and sterilization process

1) The collection

As indicated by the legislation (1,3), the collection of infective health care waste must be performed by single use packaging housed in stiff containers/bins/boxes according to art. 8 paragraph 1 of (3).

Figure 2 shows some possible packaging exploitable for this aim. In the case sharp waste materials stiff single use packaging can be used instead of flexible ones.

***Figure 2**. Example of flexible and stiff single use packaging, and of cardboard housing boxes.*

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The housing container can be made of cardboard or in reusable materials before cleansing after each use. In the case of non-reusable housing bins their weight is included in the weight of waste to be treated. Therefore, also according to circular economy principles, the exploitation of reusable containers has to be preferred.

As provided by the art. 8 paragraph 3 letter a) of (3), the temporary storage of hazardous health care waste cannot exceed five days that can be extended to 30 days for stored volume lower than 200 liters. From the storage the containers can be transported by specific trolley to the sterilization center. In the case of reusable container, the only single use packaging containing the waste are weighted and noted on specific register. Reusable containers will be cleansed and used again whereas the single use packaging will be introduced with their waste contained inside the sterilization facility and therefore processed. Figure 3 reports the scheme of the procedure described above.

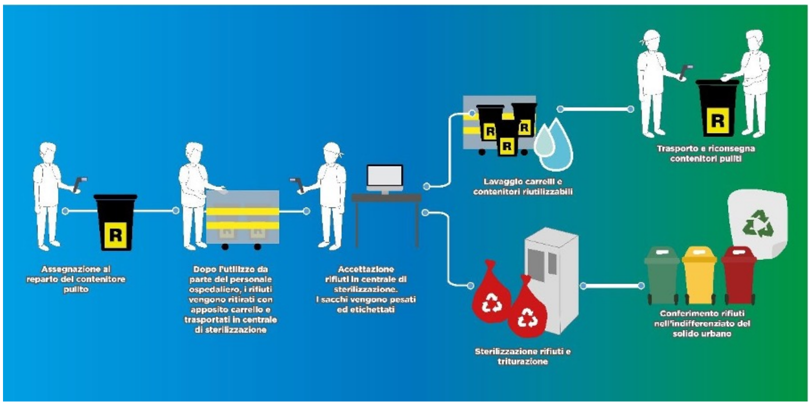

Figure 3. *Flowchart of the activity for the collection, transport and sterilization in the case of reusable containers.*

2) The sterilization

Article 2, letter m) of (3) provides that the sterilization must be performed according to what reported in the technical note UNI 10384-1:1994 (7). Section 4.3.1 of (7) reports that the sterilization of hospital waste must be performed in compliance to specific technical notes related to the sterilization agent and to the process variable. In other word, the (7) did not indicate any specific technology or process.

What is relevant for the (7) are the waste traceability, the data storage, the activities for the start-up, the validations of process effectiveness, the exploitation of biological markers as routinary controls of the process.

Furthermore, the paragraph 4.3.6.3.2 of (7) provides also physical tests with the aim of demonstrating the penetration of the given sterilization agent into the waste under treatment. In any case, the sterilization process must be able to decrease the microbial load in order to ensure a Sterility Assurance Level (SAL) of 10-6 (3)(16).

In Table 1 are reported the main sterilization technologies available at industrial scale (13) along with their main features and performances. Other processes resulted also available as the inerting by solid matrix, the biological and the ozone systems but, currently, these resulted not so largely adopted for the treatment of infective health care waste.

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Table 1. Main features and performances of sterilization processes and technologies.

Tecn./process	Pathogens abatment	Volume reduction (%)	Temp. (°C)	Time (h)	Operation
Incineration	100%	90-95	Fino a 1200	1-6	L/C
Autoclave	6-8 log_{10}	Fino 85%[a]	121-140	15–60 min.	L
Microwave	7 log_{10}	80%[a]	95-100	> 0,5	L
Depolimerization	6 log_{10}	80%[a]	180-370	1-1,5	L
Chemical	6 log_{10}	N.D.	95-155	>25 min.	L

Legend: a= after shredding; L=batch ; C=continuous.

In general, the choice of the sterilization technology/process must consider the following main criteria summarized below:

- Environmental. Among these: greenhouse emissions; aircraft pollutants; watercraft pollutants; solid waste generation; energy consumption; water consumption; volumetric reduction; pathogens load abatement.
- Economic. Among these: capital costs; operational costs; disposal costs.
- Technical. Among these: treatment effectiveness; automation level; the level of expertise requested by the operators.
- Social. Among these: level of acceptance of the technology; level of acceptance of the costs.

Based on the above listed criteria, Voudrias (13) identified as more indicate technology/ process the autoclaving performed by pressurized saturated steam.

Nevertheless, the incineration resulted nowadays the most exploited in Italy as in other countries, exploiting facility treating municipal and/or special waste as already done during the COVID-19 pandemic (14). In any case, as reported in the studies of Voudrias (13) and of Mazzei and Specchia (15), autoclave by means of pressurized saturated steam results to be the second most exploited technology worldwide after incineration.

It is also important to remark that, in general, the EU legislation on waste, makes very difficult the application of in situ-incineration for hospital waste and that, in general, sterilization technologies results characterized by a higher social acceptance than incineration. In fact, sterilization by steam resulted already largely used for the surgical tools and hence its application also to infective waste seems to be of easier implementation.

Steam sterilization resulted also suitable for the treatment of liquid infective waste as stools and urines (art. 2 paragraph d, letter 2b.2) of (3).

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Nor the technical note (7) neither the legislation (3) reported about the necessity of shredding the waste. In effect the shredding is more oriented to make difficult to identify the waste but it's advantages in increasing the sterilization efficiency is controversial. In fact, if performed before the sterilization, this can lead to a contamination of the shredder components and to generate small particles with high tendency to adhere to surfaces that sterilization mean cannot reach efficiently. After sterilization, shredding can be applied depending on the fate of the waste (15) (e.g. SRF, landfill, incineration etc. etc.). More criticism can be associated to those sterilization devices adopting shredding system installed inside the sterilization chamber. In this case the presence of blades, knifes, shaft can act as a shield preventing, from one hand, the action of the sterilization means, and from the other hand the complete removal of all the waste particles from the same sterilization chamber.

Concerning the safety of workers and operators, avoidance of preliminary shredding makes also operation and maintenance activities, both planned and emergency, safer from the biological risk perspective. Finally, in compliance with the always more stringent recycling goals imposed by the last legislations (2, 5, 8), from not shredded waste is easier to extract eventual recyclable materials. Such possibility becomes definitively more difficult if the materials are reduced in small size strongly commingled particles.

Said this, the exploitation of steam as sterilization agent is the most recommended by the several guidelines available for the specific sector. It results largely exploited from several years, and it is practically the only used for the sterilization of liner bags with high infective risk waste generated from experimental laboratories with biosafety level (BSL) from BSL-q to BSL-4 (16).

High responsibility for the operation and for the validation of the sterilization process and of its efficiency in all the different phases and activities concerns the medical director/responsible, art. 7 paragraph 6 of (3). The annex III of (3) states the procedures and the criteria for these controls along with the daily test to be performed before the activation of the sterilization facility. Such tests are already largely adopted in several Italian sterilization centers.

3) Traceability of sterilized waste

Article 7, paragraph 8, of (3) states that, without prejudice to the obligation of maintaining the loading and unloading registers, at the sterilization facility must be also maintained a register with progressively numbered sheets on which, for controls issues, must be indicated the following information:

a) Identification number of sterilization cycle.

b) Daily amount and types of waste sterilized.

c) Date of the sterilization process.

Such registers and the related traceability can be implemented by the aid of a specific informatic system able to include also the monitoring of the process and the maintenance of the established indicators.

The traceability starts from the temporary storages located inside the hospital. After being collected the waste are transported, by the specific trolley, to the check in area of the sterilization facility.

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In this area there are the following equipment:

- A scaler for the waste.
- A printer.
- A PC all-in-one.
- A bar code reader.

In the case of reusable containers, each of these will be weighed considering the tare and scanned by the bar code reader. To the amount of waste inside each container is associated a batch number to which will be associated the other specific information related to the waste necessary for its traceability as (7):

- The weight.
- The date of arrival to the sterilization facility.
- The department from which the waste was generated.
- The description of the waste (e.g. solid, glass etc. etc.).
- The number of the batch.
- The number of the sterilization cycle associate to the number of the batch.

Along with the above described information, the informatic system can also register the data of each sterilization cycle. All the data concerning the operation of the sterilization plant must be stored for at least 5 years.

Once sterilized, the waste are weighted again and then moved to the temporary storage clearly identified by labels reporting the code EWC 200301 "Mixed municipal waste". In this way ate each sterilized waste are associated both the batch and the sterilization cycle numbers.

RESULTS

Realization of an in-situ sterilization plant

One of the main data for the correct design of a new sterilization plant (Fig. 4) is the amount (kg) of waste to be sterilized per day/year taking also in consideration the maximum storage period fixed by the legislation (i.e. 5 days). Based on this information it is possible to establish the number of sterilization unit necessary for the treatment of the waste including the non-operation periods due to maintenance.

The second step consist in the identification of adequate areas/building for hosting all the sterilizations units and the related equipment including the areas for the storage of the inlet and outlet waste, for the reusable containers and the necessary room for the management of the whole system. The area/building to host the sterilization plant can also be realized by containers.

Once all the necessary permission has been obtained it is necessary to provide the site with the necessary connection to the different utilities (e.g. water, electricity, compressed air, network grid etc. etc.).

The internal volumes of the buildings hosting the sterilization equipment must be maintained at slight vacuum by the implementation of electrical fans able to allow a continuous inlet of external fresh air. The volumetric flow rate (m3/h) requested for the

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fans is determined based on the whole volume of such building and based on a multiplicative coefficient, usually not lower than 15, indicated by the current legislation (17,18). Before being eject in the atmosphere, the sucked air must be filtered by HULPA filter.

Once the building of the plant was completed, before its activation it is necessary to proceed to the necessary test as indicated by (3) and (7) and to the communication to the legal entity responsible for this activity (Region or Province). Other important aspect related to the operation of the sterilization plant is represented by the personnel protection equipment (DPI) for the operators and all the other ancillaries as: trollies; consumables like labels, liners; consumables requested for the quarterly, or every 100 cycles, test for verifying the efficiency of the facility and of the sterilization process (Annex III of (3)).

Concerning this last aspect, the number of bioindicators to be exploited during these test must be at least 1 every 200 liters of effective volume of the sterilization chamber and in any case not less than 3. Susch bioindicators must be in compliance with technical notes CEN series 866.

The training and the selection of the operators of the sterilization plant is reported in the Appendix A of (7). The skills requested for the operators concerns several aspects as:

- Fundamentals knowledge of the sterilization process and of sterilization definition.
- Knowledge of cleansing and sterilizing agents.
- Knowledge of the regulation.
- Knowledge of hazards and risks of the activity performed and of the measures and means for protecting and preventing risks and their effects.
- Ability in the use of individual and collective protective equipment (DPI) required by the legislation and available at the sterilization plant.
- Ability in the management operations.
- Training for the use of the necessary equipment.
- Basic knowledge on hospital infections and on microbiology.

For optimizing the operation of the sterilization plant, based also on its daily working hours, the whole logistic of infective hazardous health care waste needs to be reorganized. In the case of large hospitals, the operation of the sterilization plant can also be organized on 24/7.

Figure 4. *Example of a sterilization unit.*

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DISCUSSION

a) Biological, environmental and local aspects

The combustion of infective health care waste operated by the incineration process leads to the emission of several pollutant compound as reported in Table 2 (19).

Table 2. Main pollutants emitted by the different waste treatment systems (5C1a = incineration).

NFR		SNAP	
5A	Solid waste disposal on land	09 04 01 09 04 02	Managed waste disposal on land Unmanaged waste disposal on land
5B	Biological treatment of waste	09 10 05 09 10 06	Compost production Anaerobic digestion at biogas facilities
5C1a	Municipal waste incineration	09 02 01	Incineration of municipal wastes
5C1b	Other waste incineration	09 02 02 09 02 05 09 02 07 09 02 08	Incineration of industrial wastes Incineration of sludge from wastewater treatment Incineration of hospital wastes Incineration of waste oil
5C1bv	Cremation	09 09 01	Cremation of corpses
5C2	Small scale waste burning	09 07 00	Open burning of agricultural wastes
5D	Wastewater handling	09 10 01 09 10 02	Waste water treatment in industry Waste water treatment in residential and commercial sector
5E	Other waste		Car and building fires

Main pollutants	5A	5B	5C1a	5C1bi	5C1bii	5C1biii	5C1biv	5C2	5C1bv	5D	5E
NO_x			x	x	x	x	x	x	x		
CO			x	x	x	x	x	x	x		
NMVOC	x	x	x	x	x	x	x	x	x	x	
SO_x			x	x	x	x	x	x	x		
NH_3	x	x									
Particulate matter											
TSP	x		x	x	x	x	x	x	x		x
PM10	x		x	x	x	x	x	x	x		x
PM2.5	x		x	x	x	x	x	x	x		x
BC			x	x	x	x	x	x	x		x
Priority heavy metals											
Pb			x	x	x	x	x	x	x		
Cd			x	x	x	x	x	x	x		
Hg			x	x	x	x	x		x		
POPs Annex											
PCB			x	x		x	x		x		
POPs Annex III											
Dioxins			x	x	x	x	x	x	x		x
PAH			x	x	x	x	x	x	x		
HCB			x	x		x	x		x		
Other heavy metals											
As			x	x	x	x	x	x	x		
Cr			x	x	x	x	x	x	x		
Cu			x	x	x	x	x	x	x		
Ni			x	x	x	x	x		x		
Se			x	x		x		x	x		
Zn			x	x	x		x	x	x		

Concerning the emissions from the sterilization process based on autoclave with steam, on the basis of experimental analysis performed on some of the operating plants it is possible to state that:

a) *The emissions to air are usually very low* and completely removed by the exploitation of ULPA (Ultra Low Penetration Air) filters posed after the suction fan used for the air circulation in the room of the sterilization unit.

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b) The emissions to water are represented by the pollutants in the wastewater generated by the condensation of the steam used for the sterilization. *These wastewaters contain some metals at concentration significantly lower* than the limits imposed by the legislation, according to the Table 3, Annex 5, Part III of (2). Other pollutants with significant concentrations, i.e. higher than the thresholds reported in the Table 3 above mentioned, requiring treatments before discharging such wastewater in the environment, are represented by the compound of Cl, N, P and by the BOD5 and COD. For managing such wastewater three different options can be chosen: 1) Asking for special permission to the local water authority for direct discharging in the municipal sewage grid; 2) implementing chemical-physical wastewater pretreatments (e.g. resins, flocculation) for achieving the limits imposed in the above mentioned Table 3; 3) storage of the wastewater identified by the EWC 161002 "aqueous liquid wastes other than those mentioned in 16 10 01*" in tanks for their successive treatment in third parties wastewater treatment plants.

For Italy, the presence of the majority of incinerator facilities in northern regions, implies that a large part of infective waste is transported for hundred miles from southern to northern regions. This from one hand increase the atmospheric pollution due to the combustion of fossil fuels but, from the other hand, can also represent another potential risk of diffusion of biological agents in case of accidents (20). For these reasons it seems recommendable to implement the principle of proximity, already implemented by law for the municipal waste, also to the health care waste. This principle, that is compulsory for the disposal operations that must be performed in the same region from which the waste are generated, promotes the treatment of the waste as close as possible to the place of production for minimizing both costs and environmental impacts due to their transportation. The proximity principle also includes the geographic proximity, the local/ regional self-sufficiency the sharing of the necessary infrastructures among the hospitals and with the local waste management companies creating a more efficient network. Also, for this perspective, the sterilization can represent a very important tool able to modify the legal status of EWC 180103* and 180202* from special waste into EWC 200301 municipal waste treatable by the local network of facilities.

Another important aspect is related to the current costs for municipal solid waste management that in the 2021 (1) resulted on average for Italy of 38.5 €c/kg. Concerning the only collection and disposal costs for mixed municipal solid waste these resulted of 11.7 €c/kg and 4.63 €c/kg, respectively. These values are significantly lower than the fees currently applied for the management of infective health care waste ranging from 1.4 up to 1.8 €/kg.

b) Legal and medical liability

In compliance with the art. 188 of (2), the producer of the waste is responsible for its correct management. This means that the producer must provide all the necessary activities for managing the waste in accordance with the current legislation directly or by assigning their waste to companies able to pursue such issue. In the case the producer delivers their waste to an authorized company the responsibility is transferred to this company after the waste identification form (FIR) was returned duly signed by the authorized person of the company receiving the waste. Such mechanism is aimed to

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implement a fundamental principle of the EU environmental policy that is "polluter pays" by means of the application of the extended producer responsibility.

Concerning the in-situ infective health care sterilization, the responsibility is in charge to both the medical director and to the company in charge of managing the sterilization plant. Furthermore, the medical director must also provide a direct and on-time control on all the different phases referred to the management of the waste. This last aspect is practically not feasible if and extra-situ sterilization plant was adopted, also considering the higher number of subjects generally involved.

In the end, the sterilization of infective waste will differ not so much from the one already implemented for surgical instruments.

Though, it is worthy to remember that the current legislation on health care waste (3) indicates that infective waste must be incinerated and that only those sterilized can be exploited for SRF production. As already described and discussed in the previous chapters, this approach, even if aimed to pursue the maximum environmental and health protection, appears no more in line with the lates legislation that strongly promotes the introduction of circular economy concept also in this sector. In fact, after sterilization both EWC 18 01 03* and 18 02 02* assumes the legal status of municipal mixed waste EWC 20 03 01. For such waste the current legislation allows also the possibility of other recovery and/or recycling operation beyond the SRF (Solid Recovered Fuel) production, after proper treatments and selection. In this case the shredding of waste after sterilization appears not recommended.

CONCLUSIONS

The activation of an in-situ sterilization plant for infective health care waste represents a first step for the implementation of circular economy concepts also in this sector.

At world level the diffusion of this practice is continuously increasing. Nowadays about 25% of infective waste from hospitals undergoes to sterilization or similar methods for their inactivation.(21) Main finding and key factors related to the implementation of an in-situ sterilization plant for the treatment of infective hospital waste can be summarized in the following ones:

Biological aspects:

- In-situ sterilization of infective health care waste avoids the dispersion of biological agents and reduces the distance between the site of waste generation and the site of its treatment.
- Financial aspects:
  - *Decrease of weight and volume of waste*. Shredding and the adoption of reusable containers are both positive aspect able to lead to a decrease of the weight and the volume of waste to be disposed.
  - *Decrease of the transportation costs*. After in-situ sterilization the waste can be delivered directly to the municipal waste management company without the need of being compulsory transported to an incineration facility.
  - *Decrease of management costs*. The cost per kg of waste managed can be reduced also because of the legal status of municipal waste assumed after the sterilization. In those

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cases where the sterilization was implemented, the reduction of the whole management fee was reduced, on average, of 22%.
  - *Increment of economic incentives*. Sterilization facilities can also benefit of the incentives introduce by the industry 4.0 regulation.
- Environmental aspects:
  - A reduction of fossil fuel consumption due transportation is one of the main environmental and economic advantages for the implementation of an in-situ sterilization plant.
  - Emissions from the sterilization facility were not relevant and mainly concentrated on the wastewater as typical wastewater organic pollutants.
  - Possibility of using the sterilized waste to produce End-of Waste SRF according to the Italian legislation.
- Medical liability:
  - The medical liability remains substantially unchanged both for the in-situ sterilization and for the conventional management system. In fact, for the former the responsibility is transferred to the company in charge of managing the sterilization plant whereas for the latter the responsibility is in charge to the company to which the waste are transferred. In both cases, the medical director has the same responsibility related to the duly diligence of verifying the effective processes to which the waste undergoes.

Other aspects that need to be evaluated and analyzed before implementing an in-situ sterilization plant are the following main:
- The sizing of the treatment capacity of the sterilization plant also on the basis of the volume of waste to be treated;.
- The adequate availability of area for hosting both the plant and the related storage of inlet (i.e. EWC 18 01 03* and 18 0202*) but also outlet (i.e. EWC 20 03 01) waste.
- Alternative system for the management of the infective health care waste during the stop of the sterilization plant for maintenance or for other reasons.
- A given treatment overcapacity able to face emergency scenario as the COVID-19 pandemic one.
- Definition of new agreements with the manager of the facilities for the treatment of the sterilized waste with an adequate treatment capacity able to receive these new amounts.
- The evaluation of the possible increase of the TARI by the municipalities in the case the amount of EWC 20 03 01 generated by hospitals increases.
- Definition of the contract for the management of the sterilization plant by third parties.

In general, even if there still remain some aspects needing more investigation and clarification, the present study highlighted that there are many other aspects and elements making the in-situ sterilization of infective health care waste worthy to be considered.

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Pietro Manzi
Direttore Sanitario Azienda Ospedaliera di Terni
p.manzi@aospterni.it