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"CONVERTER" STERILIZER

Investigation on the effectiveness of a sterilizing process for infectious hazard sanitary waste.

Summary of the present report:

- Introduction.
- Description of equipments and process.
- Description of methodology of tests and analysis.
- Results.
- Conclusions.

INTRODUCTION

With reference to the charge letter Prot. no. 862 dated 17th December 2008, on behalf of the company Officine Meccaniche Pejrani srl (OMP), Turin, we Dr. Antonio Arnese and Dr. Ivan Cavallotti of the Second University of Naples, Department of Public Clinic and Preventive Medicine, in the date 14th and 15th January 2009 went by the Hospital Complex of the Tuscany Foundation Gabriele Monasterio Medical Research and Public Health, Hospital of Heart of the city of Massa in the Tuscany Region, in order to perform the checks of a "Converter" equipment realized by OMP in the factory of Vinovo (Turin). This equipment is finalized to the treatment of the hospital waste with infectious hazard. The investigation had, as main object, the evaluation of the sterilizing process effectiveness on hospital waste by means of "Converter" and, as a secondary purpose, the checking of the proper performance of the bioindicators that are used for the rapid verification of positive sterilization on the treated waste.

In the following, the report illustrates the main characteristics of the Converter equipments, the methodologies used for the sterilizing-process' verification, the obtained results and the conclusive considerations.

DESCRIPTION OF THE EQUIPMENTS AND PROCESS

The use of the Converter equipments **(process and equipment are covered by several international patents, among which the European patent EP 0710125, the Unites States patent US 5.800.776, Canada CA 2.167.415, etc., all having origin from the Italian deposit TO93A000547 and from the international publication WO 1994EP02357)** is finalized to the demolition of the bacterial load (bioburden) and for the obtainment of a product that is dry, of reduced weight and volume, free from pricking objects. The operation of these equipments founds on the known sterilization method referred as *"moist heat",* consisting in applying to the material under treatment (sanitary waste) a rather high temperature, in presence of water in liquid form, during a time enough long for getting the whole sterilization of the waste.

The temperature level of the sterilizing step, in the Converter equipments, is set by the manufacturer at 151°C during 3 minutes. The process develops as by the following thermal cycle, including:

- Size reduction of the waste,
- Evaporation of all liquids present in the waste,
- Heating up to the temperature of 151 °C,
- Sterilization at 151 °C with holding time of 3 minutes through dosage of evaporating water,
- Cooling down with evaporating water and unloading of the dry treated material.

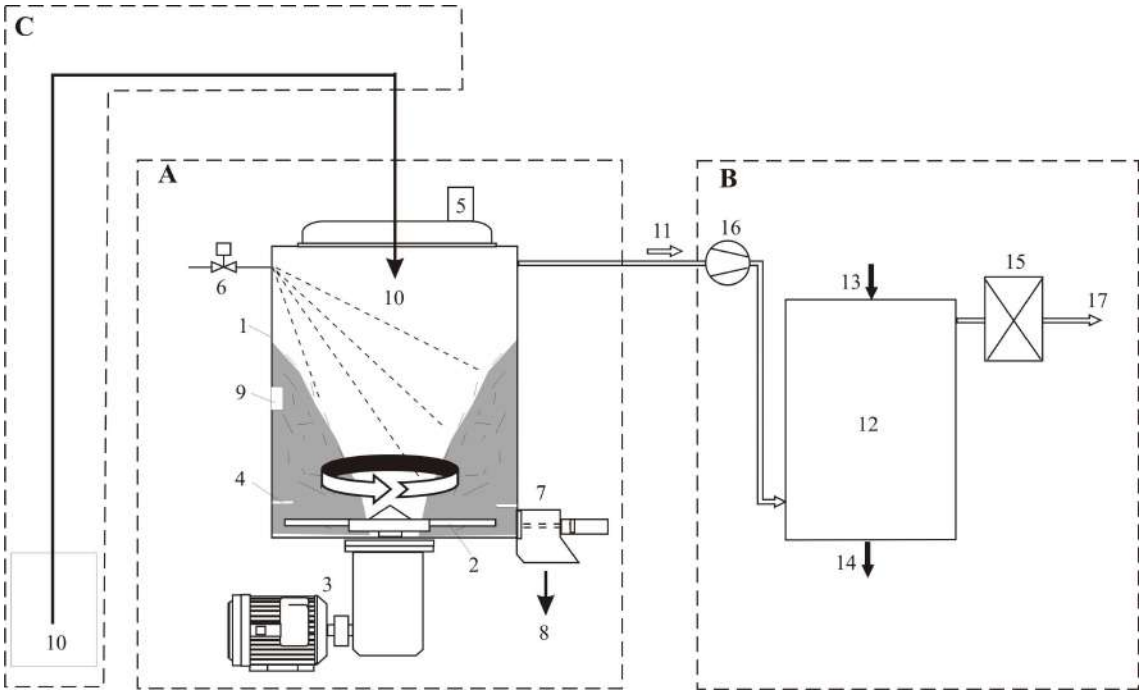
The process allows to contemporarily getting the waste reduction to small size, needles and disposable lancets included, the powdering of all glass objects, the softening of the plastic films and the elimination of all liquids, elements that on the whole contribute to the volume and weight reduction. The issued product is dry, in flocks and grains of few millimetres size, free from any particular odour, recognizable parts and sharps. Needles and lancets are transformed into not pricking particles of millimetres size.

As it appears in the following scheme, though realized in a unique block, the equipment can be considered constituted by three functional sections:

Section “A” where the sterilization is carried out,

Section “B” for ancillaries and vapours absorption,

Section “C” for the waste automatic loader (on bigger models).



In the A section we have the sterilization chamber (1) realized by a vertical cylindrical cell, endowed with a tight-seal hatch. On the bottom, there is a two-arms high speed rotor (2) operated by an external motor (3) through a tight-seal system. The rotor blades are endowed with hammers. In correspondence of the rotor, on the wall of the chamber, some stationary blades (4) lean toward the inside.

An instrument (5) is installed on the lid for the temperature measurement operated through the infrared emission that is radiated from the material in continuous mixing. As a consequence of the fast mixing provided by the high speed rotor, the mass after a short while attempts homogeneous composition and the IR instrument allows to get in real time the value of its temperature.

On the lid there are other accessories, among which a lamp for lighting the cell inside and a sight glass for examining the process progression. A water inlet (6) controlled by solenoid valve and system logic is positioned on the upper part of the chamber.

For periodic rapid tests of the sterilizing effectiveness, a kit manufactured by the firm SCM Biotech Inc. (USA) is foreseen. Precisely, MagnaAmp cod. 752018 vials

combined with vials cod. 757011, for negative colour witness as by the manufacturer instructions. SCM Biotech grants that the MagnaAmp cod. 752018 vials contain 10^6 spores of Geobacillus stearothermophilus and that satisfy the norms ISO 11138, EN 866 and the USP indications.

The vials are placed into two pockets realized in the chamber inside, suitably for granting their integrity and, in the same time, for being able to reach the same temperatures of the material during the process steps.

In the low part of the cell a valve (7) is for the automatic unloading of the treated material (8). The valve opens at the end of the treatment batch and the issued product is discharged by centrifugal force. All steps of the sterilizing treatment are performed inside the sterilization cell, without any need of material displacements, consequently the material is loaded in, and then extracted from, the same chamber where the treatment is carried out.

The sterilization cell is connected by means of the duct (11) to the B section. This one provides to condense in the scrubber (12), by means of a water shower flow (13), the vapours coming from the treatment chamber. Besides, this section allows maintaining a light negative pressure (about 50-100 mm of water gauge) in the sterilization chamber through the suction pump (16). The vent flow (17), before to be released outside, passes through a filter assembly (15) including dust filters, charcoal pellets filter, and absolute filter with DOP 99,995% efficiency or higher.
The water used in the scrubber (14) is directly sent to the sewerage or to a recirculation and cooling system, where is filtered and pumped back.

The manufacturer plans to realize the Converter equipments in various sizes and treatment capacities. The productive program includes various models distinguished with H10, H25, H50, H75, H150, H200, H500 and H1500 brand marks, where the number stays for the capacity in kg per hour of treatable waste.

As by the manufacturer documentation, in some models, by means of the accessory C, the initial loading step of every treatment cycle is performed in a mechanical way, transferring the waste (10) from a bin placed at ground level to the inside of the sterilization cell and effecting the automatic weighing of the load fed to the treatment.

The parts submitted to process and vapours are realized in stainless steel and wear-proof steel.

The Converters peculiarity is that the thermal energy required for carrying out the process – say, for the evaporation of the waste humidity, for the heating of the material up to 151 °C and for the evaporation of the water added during the sterilization step – is directly generated inside the material under treatment through frictions and shocks, be means of a high speed rotor, with transformation into heat of the electric energy absorbed by the motor.

The presence of projected fixed blades avoids the material to acquire the rotation speed of the rotor and this involves friction and heat generation between rotor and material. Also all the deformations of the material as well as the breaking to millimetre size involve heat generation.

In substance, differently from the heating by conduction – where the heat transmission speed is conditioned from factors like thermal head, surface and heat exchange coefficients – in Converters the electric energy absorbed by the motor is immediately and directly transferred to the material as heat.

The treatment cycle develops automatically, controlled by a programmable logic controller (PLC) in steps as by the following sequence.

Step 1: Waste loading. The waste is loaded into the sterilization chamber, in its original packaging, in bags or cardboards, and the lid is then closed.

Step 2: Crushing. The rotor starts and the speed gradually increases, finely grinding the material while the temperature rapidly rises up to about 100 °C.

Step 3: Evaporation. The heat generated by friction inside the material causes the evaporation of the waste humidity and the temperature remains firm at ca. 100°C.

3Step 4: Heating. Once the whole humidity has been removed, the heat that is generated causes the waste temperature to rise up to 151°C.

Step 5: Sterilization. The temperature of the material is kept firm at 151°C along three minutes by means of water dosage regulated by the IR temperature detector. The water, going in contact with the hot material, evaporates absorbing the heat that in the meanwhile is generated. As soon as it evaporates, the water is replaced by other water. In substance, in this step the water dosage is controlled so that the heat absorbed by evaporation exactly balances the heat generated in the same time by friction. This allows to both keeping wet the material and firm the temperature.

Step 6: Cooling down. The speed of the rotor is reduced and consequently also the heat generation while the mass is sprinkled with water to lower the temperature of the

material to about 100°C. In this step, the heat absorbed for the evaporation of the water overcomes the one generated by the rotor and consequently the temperature goes down.

Step 7: Unloading. The treated material is unloaded by centrifugal force through the opening of a motorized way-out valve positioned in the low part of the chamber. Once the treated material is completely discharged, the rotor stops.

Step 8: Flushing. The cell remains under aspiration and the air flow coming from the outside through the open valve eliminates the residual vapours preparing the system for the next opening. The way-out valve is then closed concluding the treatment cycle.

A substantially dry product is obtained, homogeneous under the physical aspect. Recognizable parts are not evident. The glass matters are fully powdered. The metallic parts are reduced to millimetre size, without any presence of sharp or prickly elements, because the rotor has made round all the edges. The obtained material is gathered in suitable containers and stored before to be sent to the elimination.

The duration of the cycle can vary, because the steps no. 2-3 and 4 have duration depending on the humidity and weight of the waste submitted to every single treatment. The parameters of the phase n. 5 (holding at 151°C along 3 minutes in presence of water) are fixed assuring the sterilizing effect.

On the upper part of the sterilization cell, a nozzle is dedicated to introduce, through an on-board dosing pump and a push-button on the control board, a 5% sodium hypochlorite solution (bleach). Should malfunctions occur not allowing the treatment batch to have a regular end, the product dosage shall allow to attain an emergency sterilization.

Optionally, although it’s not anyway necessary for the sterilization process that, as already said, in these equipments founds on the moist-heat method, the user can program the system so that, at every cycle start, a small quantity of 5% sodium hypochlorite solution is mixed to the waste. The amount planned by the manufacturer is 1 ml per every kg of waste.

In this case, the dosage has the function to develop a small amount of gas which disinfects all the equipment during its flowing toward the suction and filtering systems, with safety advantages for the operators during servicing and in the case of wrong operations too.

Remarks on the moist heat method and operational conditions of the "Converter" equipment

The method consists in submitting the material to be sterilized, in presence of water in liquid form, to a proper binomial time/temperature. The exposition of the waste, at enough high temperature in presence of liquid water during a time sufficiently long, causes the degradation of the microorganisms' enzymes and proteins and, consequently, their death and the spore destruction.

The sterilizing action is more rapid in comparison to the method referred as "dry-heat" (which also requires higher temperature levels and more time).

The most known devices applying the moist-heat method are the autoclaves, where steam under pressure and temperature over 100°C is used.

It important to observe that, to cause of the microorganisms' death, do not contribute neither the steam nor the pressure. This last one has only the purpose to keep the water in liquid form at a temperature over 100°C (it can be observed, from the tables of the saturated steam, that for instance at the relative pressure of 1 bar, say 2 absolute bars, the water has a boiling point of 121 °C).

In the Converter equipments no pressure is used but, when the material preliminarily dehydrated has reached the temperature set for the sterilization at 151 °C, a dosage of water allows keeping wet the material and firm the temperature. That occurs because both the water and the heat lost for its evaporation are continuously renewed.

Microbial load to be demolished and required process conditions

The term "sterile" that in common speaking is intended as "yes" or "not" requires in reality to be understood in terms of probability. This concept is on the base of the definition of "sterility assurance level". For example, a SAL = 10^{-6} means that, although a method normally considered effective is applied, the theoretical possibility that a microorganism remains alive every million performed treatments cannot be excluded.

In substance, the SAL corresponds to the safety level requested for the sterilization process. The process should consequently be realized for the elimination of the

measured or esteemed initial microbial population (bioburden) with the safety factor (overkill) correspondent to the set SAL.

The rules in force in Italy (D.P.R. n. 254/2003) require: "*The process of sterilization consists in the demolition of the microbial load such to guarantee a S.A.L (Sterility Assurance Level) not less than* 10^{-6}*. The sterilization is effected according to the norms UNI 10384/94, part one, by means of treatments including crushing and drying with the goals of rendering unrecognizable the treated material and for a better effectiveness of the treatment, as well as for the diminution of volume and weight of the waste itself."*

The afore cited UNI 10384/94 norms point out that the: *"biological population of micro-organisms able to reproduce in the waste load to be sterilized (bioburden) is conventionally fixed in* $N = 10^{12}$ *c.f.u. for each sterilization batch (c.f.u. = colony-forming units)."*

The equipments for the sterilization of the sanitary waste need therefore to realize a process suitable to destroy the microbial load, conventionally fixed in 10^{12} c.f.u., with a safety factor of 10^{-6}, therefore able to guarantee a demolition not less of 10^{18} units (say 18 logs).

MATERIALS AND METHODS

The experimental tests have been performed on equipment used for trial test at the Hospital of Earth of Gabriele Monasterio Tuscany Foundation (Converter equipment H50 mobile type, realized in an ISO 20 feet container endowed with generator group and water tank).

The Gabriele Monasterio Tuscany Foundation supplies and develops the specialized sanitary assistance previously performed by IFC-CNR in quality of Centre of Research for the supply of Sanitary Activities (**CREAS**) of national and international importance, as it's acknowledged by Decree of the Health Ministry dated 26 June 1993. The Foundation develops moreover the same activities for research, high formation and experimentation already performed by IFC-CNR when they involve a direct attention of the Regional Sanitary Service, as well as those resulting from the cooperation between IFC-CNR, University, Regional bodies and private boards, as defined through specific agreements.

The Foundation carries out its activities at the Hospital Complex of Massa, Municipality/Shire of Montepepe (already called Apuano Children's Hospital), and at the Complex of Pisa, on the CNR Research Site. The Foundation delivers specialist services, in regime of recovery and outpatient clinic, in the field of the National Sanitary Service, with special reference to:

1. Paediatric cardiology;
2. Paediatric intervention cardiology;
3. Adult cardiology;
4. Adult intervention cardiology;
5. New-born and paediatric cardio surgery (regional reference centre);
6. Adult cardio surgery;
7. Cardiovascular new-born and paediatric therapeutics;
8. Cardiovascular medicine.

All those activities are integrated with the clinic speciality and diagnostic support units (anaesthesia and reanimation, cardiovascular intervention, cardiovascular risk unit, neuro-endocrine and metabolic factors, radiology and multimodal advanced

imaging technologies, laboratory medicine). The Foundation is endowed with large advanced imaging equipments (CT-PET, PET, MRI, TAC 64 slice, GAMMA CAMERA, etc.).

The Massa Complex, site for the tests of the present report, has 71 ordinary bed accommodations, subdivided in various units between them Adult Operative Cardiology, Adult Cardio surgery, Paediatric and Adult Congenital Cardiology, Adult Intensive Therapy and Paediatric Intensive Therapy. The Massa Complex is centre of Major Cardio surgery activity and Cardiovascular surgery in Hemodynamic theatre.

During the year 2008 more than 2500 high speciality hospitalizations have been done, of which more than 2300 in ordinary regime, for a value more than 24 million Euros, about 18000 confinement days, and more than 42000 day-hospital health services, towards patients coming significantly from out the Region and, in less amount actually not-unimportant, from abroad.

From the sanitary waste coming from the a.m. activities (about 98000 kg issued in year 2007, data 2008 in consolidation progress), the tests of the present report were prepared with the infectious hazard waste coming from hospitalization units, operation theatres and out-patient' departments.

For checking the Converter sterilizing efficacy, five tests have been performed with infectious hazard waste, as by the following table.

CYCLE N.	WASTE TYPOLOGY
1	Operating theatres of Paediatric Cardio surgery and Adult Cardio surgery, Hemodynamic, Intensive therapy
2	Operating theatres of Paediatric Cardio surgery and Adult Cardio surgery, Hemodynamic, Intensive therapy
3	Operating theatres of Paediatric Cardio surgery and Adult Cardio surgery, Hemodynamic, Intensive therapy
4	Paediatric and Adult confinement departments
5	Paediatric and Adult confinement departments

For the tests, spores cultures had been prepared in laboratory, starting from 1 litre of Nutrient Broth, sterilized in autoclave at 121°C during 15 minutes. In sterile conditions, no. 8 spores strips (Oxoid RE51002) were introduced in the broth, each one containing over 10^6 live spores of Geobacillus stearothermophilus. After stirring during 30 minutes, the inoculated substratum was incubated during 72 hours at 55 °C.

The culture, suitably diluted with sterile Nutrient Broth, has been divided into eight parts of 500 ml, in sterile polyethylene bags, containing therefore each one not less than 10^6 live spores.

The testing for the sterility check has been performed on five complete treatment cycles. More particularly, before every treatment batch, the cardboards containing the Hospital Waste have been weighed, opened with the due caution (use of the Individual Personal Endowments) to extract the plastic bag with the waste, and introducing it as such into the sterilization vessel of the Converter equipment.
Being the bags transparent, we were able to easily observe the nature of the content that was representative of the typical sanitary material, with the presence of boxes for sharps (syringes, needles and disposable lancets), material for bandaging, tampons, gauzes, cotton and cellulose, diapers, paper, cannulae, catheters, blood sacks, plastic and glass phials, plastic film, etc.

For every treatment cycle, after loading the waste into the sterilization cell, we provided to add, in the upper and centre of the load, the bag containing the culture (spores of Geobacillus stearothermophilus Oxoid RE51002) prepared as previously said. As by protocol, the tests have been performed on 5 treatment cycles, adding only in one case (to the 4th cycle) a plastic bottle containing 25 ml of 5% solution of sodium hypochlorite placed on the bottom of the Converter chamber. Besides the bag containing Geobacillus stearothermophilus, in special pockets purposely realized in the Converter sterilization cell, have been inserted some vials with spores for the rapid check of the sterilization process by using a positive and a negative kit.

Besides, from the accumulation water tank, have been withdrawn no. 2 samples of recycling water, before the 4th and after the 5th cycle, in order to verify possible variations of the chemical and physical characteristics during two treatment cycles.

At the end of every cycle, directly from the cell of sterilization, have been withdrawn, under sterility condition, about 300 grams of treated material and introduced in a bag of sterile polyethylene. The bag with the sample, marked with an identification number, has been transferred, in a thermally insulated transport container, to the laboratory for the analyses.

From the special pockets of the Converter, the vials for the sterilization rapid check have been drawn out at the end of every cycle. The aforesaid vials, at the moment of the collection, were (both negative and positive kit) of amber (bourbon) colour. Also the vials of rapid check have been numbered and then sent for analysis.

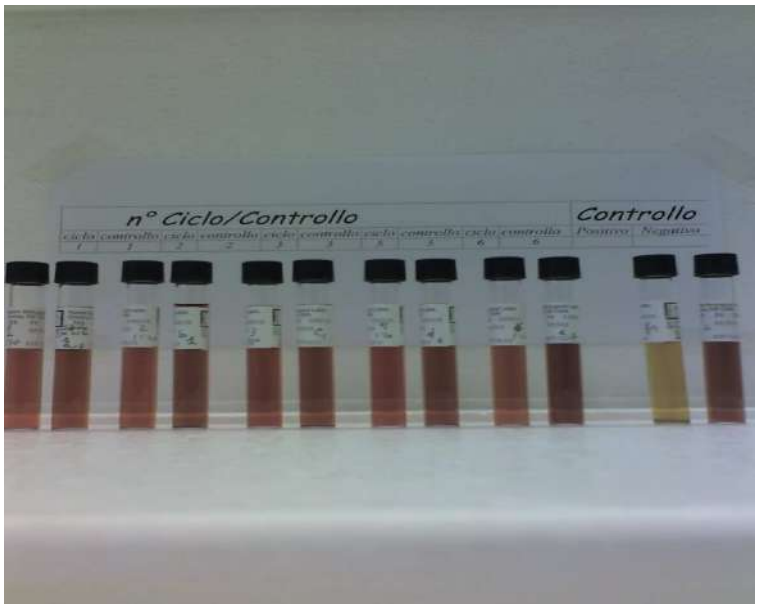
ANALYSIS OF THE SAMPLES

STERILITY TEST WITH INOCULUM

For every test, 10 grams of sample were mixed, in sterile conditions, with

triptonated water and then stirred during 15 minutes, in order to elute the microorganisms eventually stuck to the surfaces of the particles under examination, 10 ml of the elution, in double, were directly seed into 90 ml of culture broth, (Spore Strip Broth SSB OXOID).

The obtained samples were incubated during 7 days at the temperature of 55 °C and daily checked in order to verify in a macroscopic way the microbial growth, which can be observed from the colour change of the substratum from orange-red to yellow.



STERILITY CHECK BY BIOINDICATOR KIT

To the purpose, have been used MagnaAmp vial produced by SCM Biotech Inc. (USA) and characterized as it follows:

A) Vial **cod. 752018** containing 10^6 spores of Geobacillus stearothermophilus,

B) Vial **cod. 757011** colour negative witness. This vial is identical to the other one, but free from microbial load (unlike the vials type A, to be distinguished the vial has no written). This last vial is useful as colour reference (blank) because the starting violet colour can become amber (bourbon) whether the thermal insult is particularly strong, as it happens in Converter process.

With the purpose to demonstrate that the bioindicator vials don't lose their effectiveness after having been submitted to the thermal conditions of the Converter process, and consequently they can still change colour to the yellow if there is survival of bioindicator, the following method is followed.

The two MagnaAmp vials recovered at the end of the cycle, respectively type A) and type B), more one virgin of the type A) directly withdrawn from the same packaging of the bioindicator kit, are incubated at 55°C and observed for determining how and if occurs any change of colour.

The vial type A) not introduced in the Converter equipment (virgin vial) but directly withdrawn from the packaging, during the period of incubation changes colour to the yellow demonstrating the good maintenance of the bioindicator-kit packaging.

We observe the vials type A) withdrawn from the Converter after the sterilization cycle and then incubated at 55°C. If the colour is still violet (or violet-amber) and it doesn't change to the yellow after 48 hours of incubation, this means absence of spores survived to the treatment, say the sterilization is positively happened.

CHECKING OF THE WASTE HUMIDITY

Since the equipment effects the complete dehydration of the material during the treatment, the initial humidity of the waste is found by difference of weight, after having gathered completely the product issued from the treatment cycles, say by the weight difference, before and after the treatment by means of the following relationship:

% Humidity = 100 - (Dry weight / Starting weight x 100)

CHEMICAL AND PHYSICAL ANALYSIS OF THE RECYCLING WATER

On the water samples withdrawn from the tank connected to the recirculation system, the following chemical and physical determinations have been done:

- pH
- Residual free Chlorine
- COD (Chemical oxygen demand)
- Total Suspended Solids.

The a.m. determinations have been done as by the UNICHIM methods concerning the analysis of water, and following the hereinafter specified methods.

The pH has been determined as by the electro-chemical method using a glass electrode and an INFOLAB LEVEL 1 pH-meter.

The residual chlorine has been determined through colorimetric method using a DPD (N, N-diethyl-p-phenylen-diammine) solution.

The COD is performed by volumetric method dosing the substances that are chemically liable to oxidation with potassium dichromate in strong acid solution per sulphuric acid. The determination is performed by back titration, in presence of ferroine, of the excess of a known amount of potassium dichromate put to react in controlled conditions with the solution that contain the substances chemically liable to oxidation. The result is expressed in mg/l of O_2.

The total suspended solids have been determined through the gravimetric method by filtering, on a calibrated filter, a given volume of water to be analyzed. The filter is then kept in stove till firm weight at 105°C and weighed, and the amount of suspended solids calculated by weight difference.

RESULTS AND CONCLUSIVE CONSIDERATIONS

Aspect characteristics of the treated material

To the observation, the material was looking (in all the performed tests) homogeneous, finely minced in small grains and flocks, free from recognizable parts, light gray colour, free from any appreciable humidity to the touch, practically dry. After the sampling, the material was automatically discharged and then weighed.

The typology of the starting material, the weight before and after the treatment, as well as the time of starting and end of the treatment, with the initial humidity of the same material (calculated by weight difference before-after), are shown in the following table:

CYCLE No.	WASTE TYPOLOGY	Addition of 5% sodium hypochlorite	date	Time cycle starting	Time cycle ending	Load Kg	Kg issued after treatment	Humidity % by weight
1	Operating theatres of Paediatric Cardio-surgery Adult Cardio-surgery, Hemodynamic, Intensive Therapy	NO	14/01/ 2009	17.30	18.15	17.0	11.0	35.29
2	Operating theatres of Paediatric Cardio-surgery Adult Cardio-surgery, Hemodynamic, Intensive Therapy	NO	14/01/ 2009	19.00	19.17	18.5	14.0	24.32
3	Operating theatres of Paediatric Cardio-surgery Adult Cardio-surgery, Hemodynamic, Intensive Therapy	NO	14/01/ 2009	19.42	20.10	18.3	11.0	39.80
4	Paediatric and Adult confinement departments	25 ml	15/01/ 2009	9.45	10.02	19.0	14.5	29.68
5	Paediatric and Adult confinement departments	NO	15/01/ 2009	10.29	10.51	19.3	14.5	24.87

CYCLE No	WASTE TIPOLOGY	Addition of 5% sodium hypochlorite	Addition of bioindicator	Incubation at 55°C during 7 days	Indicator development (change of colour)	Positive sterilization
1	Operating theatres of Paediatric Cardio-surgery Adult Cardio-surgery, Hemodynamic, Intensive Therapy	NO	YES	YES	Absent	YES
2	Operating theatres of Paediatric Cardio-surgery Adult Cardio-surgery, Hemodynamic, Intensive Therapy	NO	YES	YES	Absent	YES
3	Operating theatres of Paediatric Cardio-surgery Adult Cardio-surgery, Hemodynamic, Intensive Therapy	NO	YES	YES	Absent	YES
4	Paediatric and Adult confinement departments	25 ml	YES	YES	Absent	YES
5	Paediatric and Adult confinement departments	NO	YES	YES	Absent	YES

CYCLE No.	WASTE TYPOLOGY	Addition of 5% sodium hypochlorite	pH	COD mg/l O_2	Residual free chlorine mg/l Cl	Total suspended solids mg/l
4	Paediatric and Adult confinement departments	25 ml	7,48	24	<0,05	2
5	Paediatric and Adult confinement departments	NO	7,44	40	<0,05	4

Sterilizing effectiveness resulting from bioculture

In no case we had growth of the biological indicator and therefore it is shown in practical way the effectiveness of the sterilization process of the Converter equipments starting from a bioindicator containing 10^6 live spores of Geobacillus stearothermophilus per each waste load.

The addition of sodium hypochlorite is not decisive for the sterilizing effect, because the sterilization is also achieved without it.

Sterilizing effectiveness resulting from the bioindicator kits

The bioindicator kit MagnaAmp vials inserted before the sterilization process and then withdrawn at the end of the treatment, although were amber (bourbon) coloured, after incubation did not change to yellow colour. That signifies that the sterilizing treatment was positively carried out.

Keeping of effectiveness of MagnaAmp kits

The seeding tests with live spores of bacillus stearothermophilus, in the kits preventively submitted to Converter process during the test cycles, allow affirming that they don't lose effectiveness in consequence of the strong thermal insult and that the capacity to indicate the situation of missed sterilization is still active.

Humidity in the starting waste

As shown in the table, in the five tests the starting waste humidity was respectively 35,29; 24,32; 39,80; 29, 68; 24,87%.

Conclusions

The tests performed on the Converter equipment realized by Officine Meccaniche Pejrani (OMP) in endowment at the Hospital of Earth of Massa have been done with a regime plant and in condition of normal load. No one spore of the inserted 10^6 live spores of Geobacillus stearothermophilus as sterilization indicator has survived in any one of the monitored 5 treatment cycles.

Besides, the spores vials used for the rapid check of positive sterilization resulted suitable for the purpose, because from the performed laboratory tests they resulted active both for the negative and positive check. In fact the vials controlled in laboratory, after the Converter treatment, were still suitable to correctly provide change of colour.

As far that the recirculation water is concerned, a little increase of the pollutants levels is detected, expressed by the light increase of the COD value during two subsequent cycles. The examined parameters enter however in the limits accepted by the rule D. Lgs 152/06, and can be sent to the sewerage system or as well through cleared firms as waste-water.

In conclusion, it is possible to affirm that the examined plant is able to guarantee both the sterility of the treated waste as well as, through its size reduction and dehydration, a remarkable reduction of weight and volume facilitating the disposal operations, without further risks for the operators.

The analysts **Director**

Dr. Ivan Cavallotti **Prof. Paolo Marinelli**

Dr. Antonio Arnese