

Gamma Sterilization of Health Care Products and Its Efficacy

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Abstract: *Different single-use health care products were irradiated with different doses. For irradiation of the products was used the GU-3 gamma irradiator (with Cs-137) installed in the Institute of Applied Nuclear Physics in Tirana, Albania. The applied rotation technique provided an absorbed dose uniformity 106% and average dose rate 4.68 Gy/min. Determination of health care products sterility was carried out in the Institute of Public Health according to a specific method. Sterility examination was performed almost one year after irradiation. From the study of results was confirmed that the use of gamma irradiation, to ensure the sterility of the products, is an effective method.*

Keywords: medical devices, gamma sterilization, culture medium, absorbed dose.

1. Introduction

Sterilization is determined as any process that effectively kills or eliminates almost all microorganisms like fungi, bacteria, viruses, spore forms etc.

There are many diverse sterilization methods depending on the aim of the sterilization and the material that will be sterilized. The selection of the method alters depending on materials and devices for giving no harm. The methods are mainly: dry heat, ethylene oxide (EtO), e-beam and gamma sterilization [7].

Gamma irradiation does have some significant advantages over other methods of producing sterile products that include: better assurance of product sterility; no residue like EtO leaves behind; more penetrating than E-beam; low-temperature process.

Radiation sterilization, as a physical cold process, has been widely used in many developed and developing countries for the sterilization of health care products [3].

Commercial radiation sterilization has been used for more than 50 years. Over the decades, there has been enormous growth in the disposable medical products market. With this, there has been significant progress in the use of ionizing radiation as a method for sterilization. At present, 40–50% of all disposable medical products manufactured in North America are radiation sterilized [5], [2].

There are now 160 commercial gamma irradiators for radiation sterilization operating in 47 countries worldwide. Syringes, surgical gloves, gowns, masks, sticking plasters, dressings, medical ‘tetra packs’, bottle teats for premature babies, artificial joints, food packaging, raw materials for pharmaceuticals and cosmetics, and even wine corks, are gamma sterilized. An increasing number of e-beam accelerators are also being operated, but at present e-beam is used for only a minority of radiation sterilized products [4].

Ionizing radiation produces ions by knocking electrons out of atoms. These electrons are knocked out violently, and strike an adjacent atom and either attach themselves to it, or dislodge an electron from the second atom. The result is ionic energy that becomes converted to thermal and chemical energy. This energy kills microorganisms by disruption of the DNA molecule, therefore preventing cellular division and propagation of biologic life [8].

2. Material and methods

A sterile product is one that is free from viable microorganisms. Items produced under controlled manufacturing conditions can, before sterilization, have microorganisms on them, although ordinarily in low numbers. Such products are determined non-sterile. The purpose of sterilization processing is to destroy the microbiological contaminations on these non-sterile products [3].

In this study were used different contaminated medical products like syringes, serum tubes, surgical threads and gloves, needles etc. They were packaged in sealed plastic bags like in photo 1.



Photo 1: Packaged medical products

This way of packaging protects medical devices before, during and after irradiation from contamination.

Dose, dose rate and dose distribution are the main physical parameters in the radiation sterilization process. The dose distribution is determined by the Dose Uniformity Ratio

(DUR). The DUR is the ratio between the maximum and minimum dose needed to effectively process a product. The DUR is not as crucial for materials which have a good tolerance to irradiation; however, devices made of materials which have a limited resistance to irradiation require an optimal DUR to prevent unacceptable levels of degradation [9].

Several types of microorganisms, mainly bacteria and, less frequently, moulds and yeasts, have been found on many medical products [1]. Complete eradication of these microorganisms (sterilization) is essential to the safety of medical products. It depends from the absorbed dose.

Earlier, a minimum dose of 25 kGy was routinely applied for many medical products. Now, as recommended by ISO 11137 (1995) and EN 552 (1994) the sterilization dose must be set for each type of product depending on its bioburden (the population of microorganisms before irradiation). All sterilization standards consider 'dose' as a key parameter in order to determine if a product is sterile [1], [3].

2.1 Radiation Method

Before irradiation of real materials it was performed the calibration of ECB dosimeters and was determinate the DUR. Products were irradiated using the gamma irradiator GU-3 installed in the Institute of Applied Nuclear Physics (with Cs-137 and energy 0.66 MeV), with radiation technique and geometry according to figure 1.

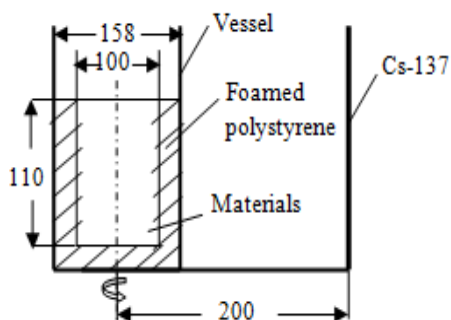


Figure 1: Irradiation technique and geometry (dimensions are in mm)

During the irradiation time, the vessel with materials inside was rotated around its vertical axe for ensuring good absorbing dose uniformity. According to the above recommended standards for irradiation of medical products was used the dose range (21÷27) kGy, the dose rate P=4.68 Gy/min and DUR =106% [6]. One year after irradiation, medical products were sent to the Institute of Public Health in Tirana, Albania, for sterility test.

2.2 Sterility Test

The aim of this test is to detect the presence of viable bacteria on the product (after sterilization). The test for sterility is carried out under aseptic conditions. Two mediums are used:

- fluid thioglycollate medium that is intended for the culture of anaerobic bacteria but it will also detect aerobic bacteria;
- soya bean casein digest medium suitable for the culture of both fungi and aerobic bacteria.

Direct inoculation of the culture medium, is the method used for sterility test. This method is based upon total immersion of the sample in a culture medium. After this the inoculated medical samples were incubated for 14 days at 30-35°C. The cultures were observed several times during this period [10]. Description of the testing method schematically is given in figure 2.

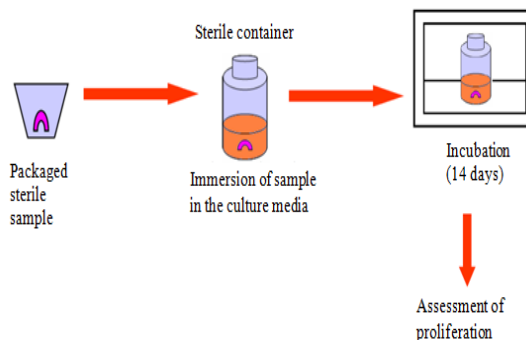


Figure 2: Sterility test of the samples

3. Results and Discussion

During the incubation period the culture media was observed for growth. It should be generally clear and transparent against a light source. Turbid (cloudy) areas in the media are indicative of microbial proliferation. From the investigation was noticed that the solution with irradiated products was clear. Conversely, the solution with non irradiated products (control indicated with K) resulted cloudy (contaminated with microorganisms). Photos 2, 3, 4, 5 shows the results obtained.



Photo 2: Products irradiated with dose 27 kGy



Photo 3: Products irradiated with dose 21 kGy

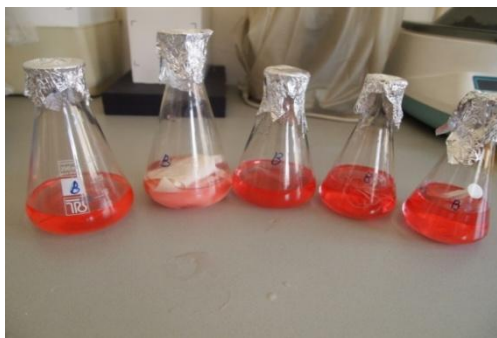


Photo 4: Products irradiated with dose 25 kGy



Photo 5: No irradiated products (Control)

Medical products that resulted sterilized with different doses were:

- vignon, serum tube, needle, Petri dish, surgical gloves and thread irradiated with dose 27 kGy (photo 2);
- syringe, serum tube, surgical thread and gloves, needle irradiated with dose 21 kGy (photo 3);
- syringe piece, surgical thread, needle cap, surgical gloves, serum tube irradiated with dose 25 kGy (photo 4);

4. Conclusions

- The rotation radiation technique used, provided a good dose uniformity (DUR=106 %);
- The sterility test made one year after irradiation (with dose 21÷27 kGy) indicated good results;
- The gamma sterilization of medical products is a good, simple, quick and safe method.

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Marsida Klemo was graduated in Physics (5 years) from Faculty of Natural Sciences, University of Tirana, during 2001-2007. From the same Faculty she received master of second level and doctorate degree respectively in 2009 and 2014. She has published a number of articles in national and international journals. Also she has participated in many international and national conferences. From 2008 she works as a physicist lecturer in Alexander Moisiu University, Durres, Albania. Actually she is Head of Engineering Sciences Department, Faculty of Professional Studies.

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