(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.

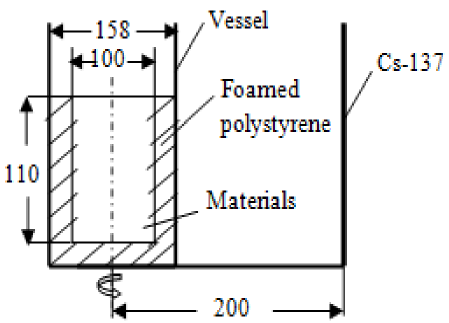

Figure 1: Irradiation technique and geometry (dimensions are in mm)

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.

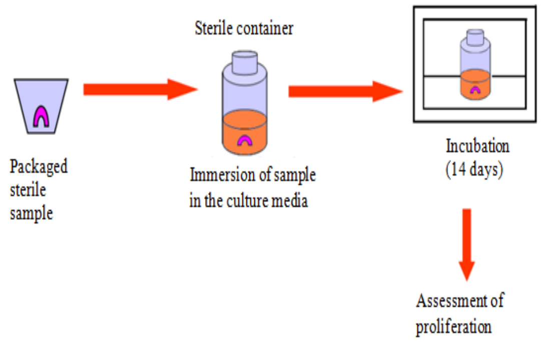

Figure 2: Sterility test of the samples

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 (contamined 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

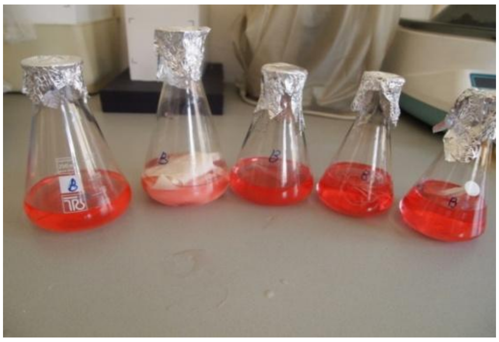

Photo 4: Products irradiated with dose 25 kGy

Photo 5: No irradiated products (Control)

Medical products that resulted sterilized with different doses were:

- vigon, 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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