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# Gamma radiation effects in packaging for sterilization of health products and their constituents paper and plastic film

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ABSTRACT

The integrity of materials containing packaging (natural or synthetic polymers) is essential to keep the aseptic condition of commercialized products (health care products, food and pharmaceuticals). The objective of this paper was to study gamma radiation effects (25 kGy, 40 kGy and 50 kGy) on the main properties of paper and multilayer films (polyester and polyethylene). Paper and multilayer films are components of packaging (pouches) for radiation sterilization containing medical equipment or products. Paper was the more radiation sensitive among the studied materials and radiation effects were more pronounced at brightness, pH, tearing resistance, bursting strength and tensile strength. Concerning plastic film, no pinholes were induced by radiation and the effects on the tensile strength were not significant. Although the seal strength packaging (pouches) decreased according to increasing dose, the sealing integrity was preserved.

## 1. Introduction

Radiation sterilization is a common technology for microbial inactivation for different products. Although 25 kGy is the recommended dose for sterilization of healthcare products, it is possible and sometimes necessary to use doses higher than this. Dose and dose uniformity requirements for the intended items are among the criteria to be achieved and the compatibility of packaging material is necessary for safety reasons.

Another issue is the variation of doses during radiation processing in commercial plants. What variation of dose is safe? International standards for radiation sterilization ask for evidences of a minimum dose of 25 kGy. On the other hand, in order to ensure the safety of sterile products many authors performed their experiments extrapolating the doses from 25 kGy up to 60 kGy or higher (Demertzis et al., 1999; IAEA, 2008; Porto, 2013).

The evaluation of packaging materials is also very important for a safety application of radiation for healthcare products sterilization. The effects of gamma irradiation on compositional changes in plastic films were reported by Demertzis and co-authors, who applied 44 kGy at several polymers. Since the late fifties radiation effects on polymers were studied and the relative stability of twelve types of plastics were published in 1961 (Krasnansky et al., 1961). They found that containing conjugated ring systems, ionic bounds and chlorine in side groups were the most stable polymers. Random degradation of polymers (cellulose) was carefully demonstrated by Ershov, using the molecular mass distribution factor (Ershov, 1998).

It is well known that polymers can be cross-linked when exposed to radiation or chain scission as the opposite effect. Regarding packaging, there is a lot of interest since irradiation processing for sterilization is an increasing technology for varied items. DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (2013) demonstrated radiation effects onto Tyvek® until 100 kGy. According to DuPont after exposure to gamma radiation up to 100 kGy, Tyvek® maintains its superior microbial barrier and the impact on strength properties is limited.

The objective of this paper was to study radiation effects onto some mechanical, chemical and optical properties in a packaging in order to ensure the quality of packaging for protecting health care products after irradiation with some extrapolation of sterility usual doses (25 kGy, 40 kGy and 50 kGy).

## 2. Methodology

### 2.1. Sample

Packaging system, for sterilized medical devices, was the target material during this study. The packaging was provided by the manufactory, as an envelope form, consisting of paper and plastic multilayer film. The paper was composed of conifers fibers (pine) and the plastic layer was formed by polyester and polyethylene polymers (Fig. 1). The samples for analysis were taken from the same region of

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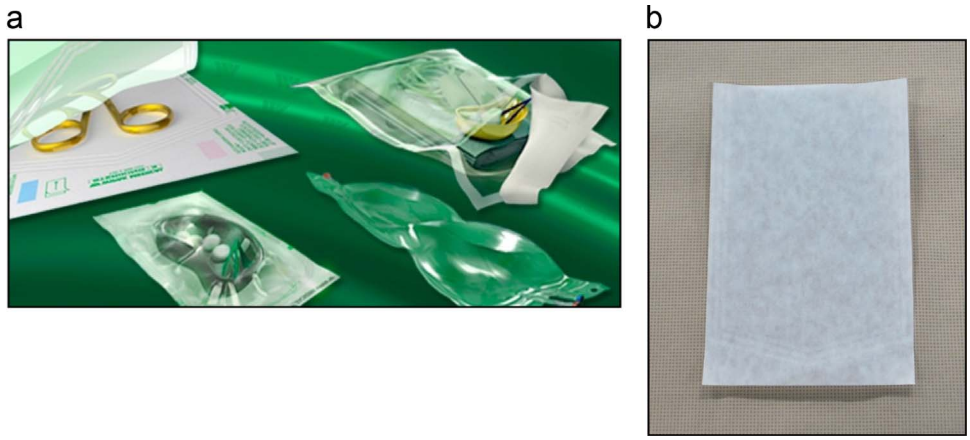


**Fig. 1.** Typical examples of packaging protecting healthcare products: (a) some commercial packaging (Winpak, 2013) and (b) the sample studied by the authors.

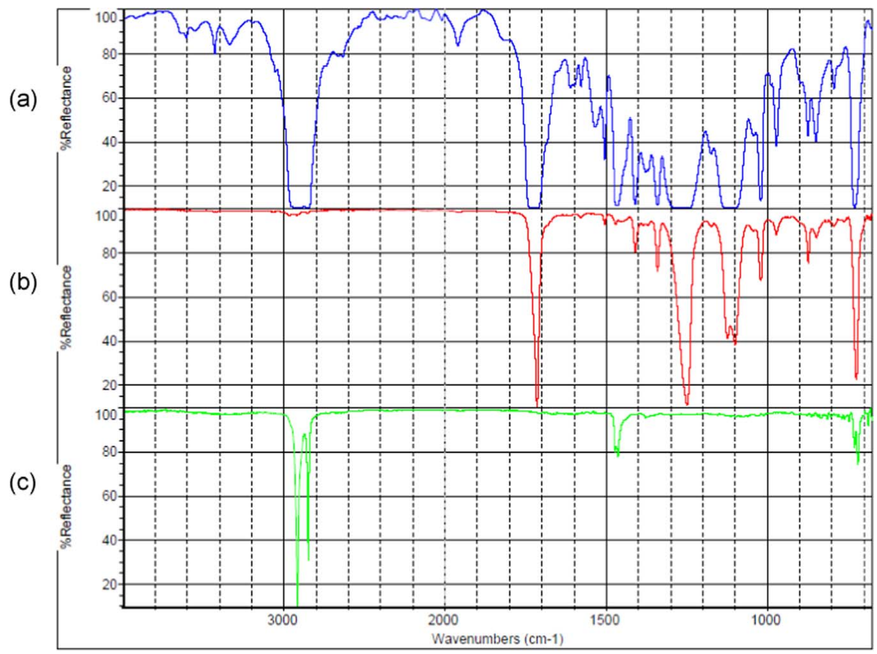


**Fig. 2.** Infrared spectra of plastic film (a) “full”, (b) “front” and (c) “back”.

**Table 1**
Radiation effects for the studied properties of the paper.

| PAPER | | | | | | |
|---|---|---|---|---|---|---|
| **Tests** | **25 kGy** | | **40 kGy** | | **50 kGy** | |
| | **Non irradiated** | **Irradiated** | **Non irradiated** | **Irradiated** | **Non irradiated** | **Irradiated** |
| Bursting strength, kPa | 367.5 (49.2) | 328.2 (34.9) | 384.8 (18.9) | 289.9 (38.9) | 387.6 (40.7) | 302.2 (39.2) |
| Tensile strength, kN/m | | | | | | |
| −machine direction | 8.07 (0.49) | 7.47 (0.44) | 7.94 (0.27) | 6.95 (0.66) | 7.50 (0.50) | 6.61 (0.49) |
| −cross direction | 3.78 (0.17) | 3.50 (0.23) | 3.74 (0.27) | 3.42 (0.16) | 3.71 (0.21) | 3.26 (0.20) |
| Tearing resistance, mN | | | – | – | | |
| −machine direction | 601.7 (20.3) | 484.0 (40.5) | | | 543.5 (22.1) | 373.4 (16.2) |
| −cross direction | 686.7 (32.8) | 555.9 (29.5) | | | 678.9 (22.0) | 419.8 (16.1) |
| Air permeance −Method Bendtsen, μm/Pa s | 10.41 (0.34) | 10.72 (0.14) | – | – | 11.08 (0.67) | 10.77 (0.55) |
| pH of aqueous extracts – hot extraction | 6.25 (0.04) | 5.68 (0.02) | – | – | 6.34 (0.09) | 4.76 (0.10) |
| Diffuse blue reflectance factor – ISO brightness, % | 83.8 (0.1) | 79.7 (0.1) | 83.7 (0.1) | 79.0 (0.3) | 83.7 (0.1) | 77.2 (0.1) |

Notes:
(a) The numbers in brackets refer to the standard deviation of ten measurements for brightness testing and tensile strength; six measurements for tearing resistance and air permeance; five measurements for bursting strength test and three measurements for pH;
(a) The values obtained for diffuse reflectance factor in the blue (brightness) were UV calibrated which means that the brightness measurement performed with the presence of the UV filter.

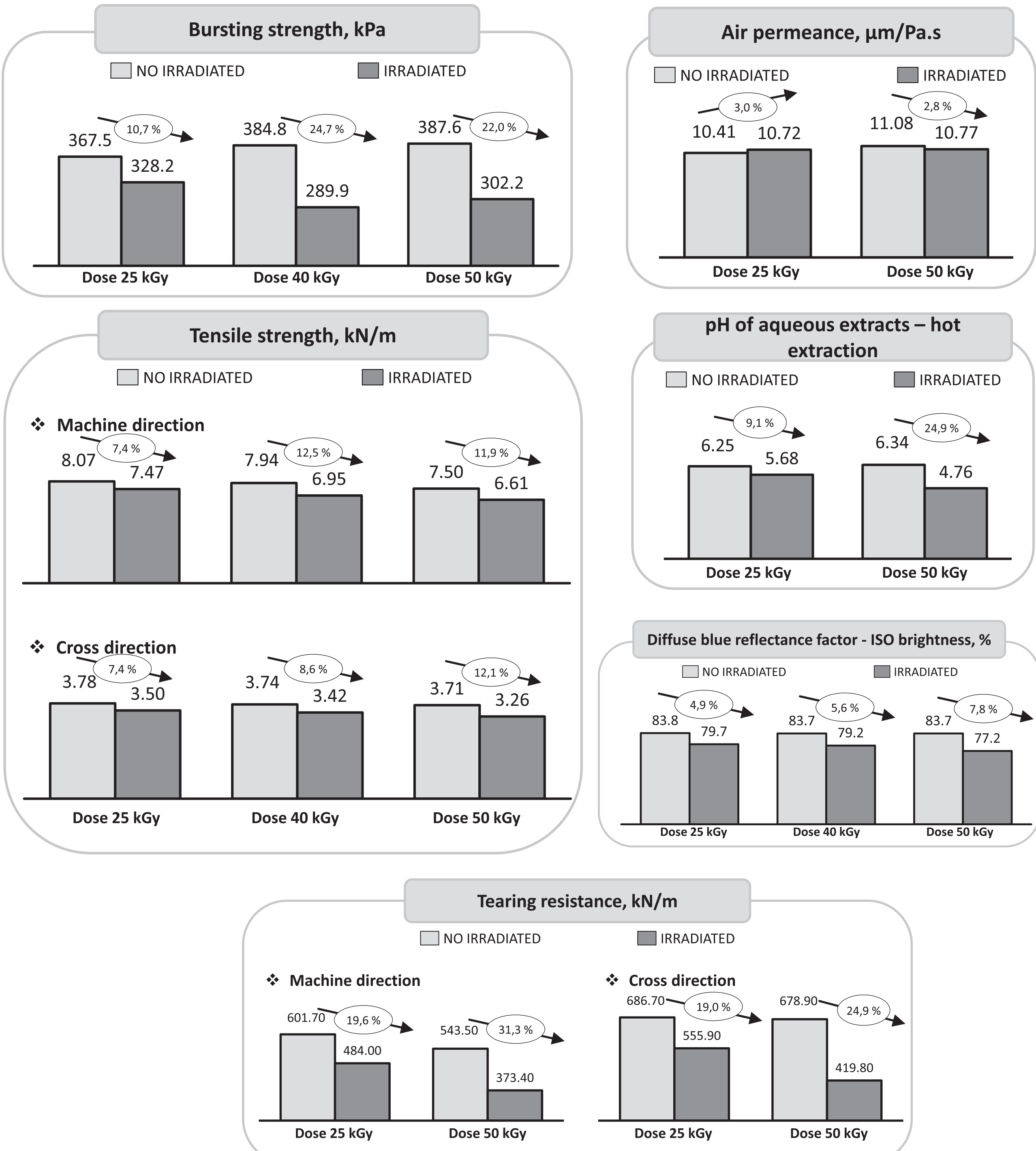


**Fig. 3.** Radiation effects obtained for bursting strength, tensile strength, tearing resistance, brightness and pH.

the package, one being subjected to irradiation and the other was the control (non-irradiated). This procedure was realized due to the non-homogeneity of the paper which could affect the comparison of irradiated and non-irradiated test results.

### 2.2. Irradiation

The packaging was irradiated with 25 kGy, 40 kGy and 50 kGy. The irradiator used in the study was cobalt-60 source, Gammacell 220 and Series number 142 (12 kCi; 8.5 kGy/h), at Radiation Technology Center (CTR-IPEN). Perspex dosimeters were used during irradiations, Harwell Red, KZ Type −4034 Batch.

### 2.3. Sample characterization (paper and multilayer film)

#### 2.3.1. Paper

- Grammage (ABNT NBR NM-ISO 536,1998) and thickness (ABNT NBR ISO 534, 1998): using an analytical balance and micrometer;
- Fibrous composition (ABNT NBR 14129-1, 1998): with an optical microscope, Leica - DM 4000 B, coupled with a DFC 310 FX digital camera and software LAS version 3.8.0.

**Table 2**
Radiation effects on some properties of plastic film.

| Multilayer film | | | | | | |
|---|---|---|---|---|---|---|
| **Tests** | **25 kGy** | | **40 kGy** | | **50 kGy** | |
| | **Non irradiated** | **Irradiated** | **Non irradiated** | **Irradiated** | **Non irradiated** | **Irradiated** |
| Pinholes | Absent | Absent | Absent | Absent | Absent | Absent |
| Tensile strength, N | | | – | – | | |
| – machine direction | 49.99 (1.21) | 49.74 (2.30) | | | 40.05 (1.54) | 38.93 (1.44) |
| – cross direction | 37.78 (1.19) | 39.92 (2.03) | | | 37.95 (1.16) | 37.02 (1.61) |

**Note:** The numbers in brackets refer to the standard deviation for six measurements tensile strength (25 kGy) and ten measurements after 50 kGy and five measurements for pinholes.

**Table 3**
Radiation effects onto the properties of the studied packaging.

| Packaging | | | | | | |
|---|---|---|---|---|---|---|
| **Tests** | **25 kGy** | | **40 kGy** | | **50 kGy** | |
| | **Non irradiated** | **Irradiated** | **Non irradiated** | **Irradiated** | **Non irradiated** | **Irradiated** |
| Sealing integrity | No leakage | No leakage | No leakage | No leakage | No leakage | No leakage |
| Sealing resistance, N | | | – | – | | |
| – top | 7.59 (0.70) | 7.43 (0.96) | | | 6.69 (0.17) | 6.80 (0.24) |
| – right side | 5.01 (0.38) | 4.82 (0.23) | | | 5.17 (0.41) | 4.79 (0.50) |
| – left side | 5.09 (0.50) | 4.92 (0.53) | | | 5.21 (0.52) | 4.74 (0.26) |

**Note:** The numbers in brackets refer to the standard deviation of ten measurements for the sealing resistance test and five measurements for sealing integrity test.

#### *2.3.2. Multilayer film*

- Grammage (ABNT NBR NM-ISO 536, 1998) and thickness (ABNT NBR ISO 534)
- Types of plastic film polymers - infrared spectroscopy (IR) with Microscope (610IR) coupled to the infrared spectrophotometer with Fourier transformed (660IR); Agilent brand; model 610IR and 660 IR. These analyzes were performed at the Laboratory of Chemical Analyses of IPT. Attenuated Total Reflectance (ATR) was applied in order to analyze the front and the back of the plastic film.

### *2.4. Tests on packaging and its constituents (paper and multilayer film) irradiated and non irradiated*

#### *2.4.1. Packaging*

Sealing resistance (Annex E of the standard ABNT NBR 14990–8:2004).

Sealing integrity (Annex F of the standard ABNT NBR 14990–8:2004): a red dye solution was introduced, using a suitable syringe, into the center of the packaging, on the side of the plastic film and it was checked if there was penetration of dye through the sealing area.

#### *2.4.2. Paper*

Bursting strength (ABNT NBR NM-ISO 2758, 1998): it was bombed a hydraulic fluid at a constant speed by expanding the circular elastic diaphragm which contains the specimen until rupture of the specimen. We used the Mullen Tester equipment, Regmed brand and MTA 2000 P model. Tensile strength (ABNT NBR NM-ISO 1924-2, 1998): dynamometer used the EMIC brand and DL 500 model, with a 10 kg load cell and strip specimens of 15 mm width. Tearing resistance (ABNT NBR NM-ISO 1974): *Elmendorf* method used 8 sheets that after an initial cut were ripped at a fixed distance, using a pendulum to apply force to tear the movement in a plane perpendicular to the initial plan. The equipment used was the Elmendorf Tearing Tester, Thwing – Albert Instrument Co brand. Air permeance – Método Bendtsen (ABNT NBR 14255): used a standard pressure of 1.47 kPa in the inner area of the ring and measuring the flow velocity of air passing between the ring and the specimen. The equipment used was the Bendtsen, Andersson and Sorensen Copenhagen brand, 6 No. 12746 model. Diffuse blue reflectance factor - ISO brightness (ABNT NBR NM-ISO 2469, 2004): the reflectance factor is measured at a wavelength of 457 nm. The equipment used was the Elrepho Reflectometer 3000, Datacolor brand, the incidence of light is diffuse and reading is made 0°. pH of aqueous extracts – hot extraction (ABNT NBR NM-ISO 6588-2, 2007): extraction of paper with 100 mL hot water for an hour, a mass of 2 g of paper. Measure of aqueous extract pH with a pHmeter and a combined glass electrode.

#### *2.4.3. Multilayer film*

Pinholes (Annex B of the standard ABNT NBR 14990–8:2004): under the plastic film wrap placed a sponge set of blocks cellulose soaked in a red aqueous dye amaranth solution containing 0.005% of cetrimide as a wet agent and a steel plate with a total mass of 800 g ± 50 g. The sponge and plate were removed and examined the penetration of the dye into the absorbent paper which was placed under the plastic film in a flat surface of a piece of glass. Tensile strength (ASTM D 882-02, 1997).

The tests performed in this study are used to verify the conformity of the packaging and its components (paper and plastic laminate film) with respect to international and national standards: ISO 11607:2006 - *Part 1and Part 2;* EN 868 - *Part 5*; ABNT NBR 14990:2013 - *Part 8 and Part 3.* The packages are suitable for use if they comply with the conformity standards.

To determine the parameters, the package was conditioned and tested in standard atmosphere at 23 ± 1 °C and 50 ± 2% relative humidity, and time conditioning of the test specimens of at least 24 h, except the parameters pH and pinholes. All equipment used in the analyzes were calibrated by calibration laboratories accredited by the Brazilian Calibration Network (RBC).

## 3. Results and discussion

### *3.1. Characterization*

#### *3.1.1. Paper*

The paper was manufactured with bleached chemical pulp, coming from the sulfate process. The paper fibers were obtained from conifers (pine). In the photomicrographs of fibers it was observed the presence of aerolada score, typical of tracheid of coniferous fibers. Conifers fibers are long (on average 3 mm). The packaging paper presented 62.9 (0.2) g/m$^2$ for grammage and 0.089 (0.001) mm thickness. Long fibers manufactured papers generally present better strength properties than those made with short fibers.

#### 3.1.2. Multilayer film

The grammage of plastic film was 56.3 (0.5) g/m$^2$ and 0.058 (0.002) mm thickness.

The composition of the plastic film was investigated by FTIR in transmittance mode. In this technique, the spectrum obtained corresponds to the whole components ("full plastic film"). In order to verify the presence of different layers constituents of the plastic film, FTIR spectra from both faces of film were collected using the ATR accessory. These spectra were called "front" and "back".

The infrared spectrum of the plastic film "front" is characteristic for poly(ethylene terephthalate) and the spectrum of plastic film "back" is typical for polyethylene (Figs. 2**b and c**, respectively). The infrared spectrum of "full" (Fig. 2**a)** plastic film corresponds directly to the sum of "back" and "front" spectra. This result suggests that the plastic film do not have inner layers with other types of polymers.

### 3.2. Radiation effects on materials

#### 3.2.1. Paper

The obtained data for understanding the effects of radiation in the studied material was presented at Table 1 **(**paper from the package). The results represent the selected parameters, as main indicative of resistance after 25 kGy, 40 kGy and 50 kGy.

For the irradiated paper sample it was observed that air permeance test was very little affected by radiation while pH, bursting strength, tearing resistance and tensile strength were significantly decreased after irradiation (25 kGy and 50 kGy). At the 40 kGy there was also a significant decrease for all the obtained results. The data displayed as Fig. 3 show the effects of radiation onto some of the physical and optical properties of the paper in the packaging studied.

The tearing resistance is a property that depends primarily on the integrity of the fiber, while the tensile strength depends more on the paper fibrous array. Since the variation of tearing resistance values was higher than the tensile strength (Fig. 3) it can be inferred that the gamma irradiation induced modification into cellulose fibers, under the studied conditions.

The bursting strength is a characteristic of both the integrity of the fiber as the fibrous paper arrangement and is also a feature that has undergone a considerable change of 11% with 25 kGy, 25% with 40 kGy and 22% with 50 kGy (Fig. 3). The small variation obtained for the air permeance values, a property that depends on the fiber arrangement of the paper, confirms the fact that the fibrous array was less affected by the radiation compared to general obtained values.

D'Almeida et al. (2009) showed a decrease in strength parameters to draw and zero span on sheets of paper formed under laboratory conditions after 9 kGy. According to this study, fiber strength was more affected than the sheet resistance, probably due to cleavage of the cellulose molecule.

According to Ershov (1998), the main ionizing radiation effects on cellulose (as well as other polysaccharides) are related to the scission of the polymer chain, meaning degradation by changing the physical-chemistry properties of the polymer (structural, strength mechanical, solubility in different media, reactivity, etc.). They showed through their study that the degradation process in a macromolecule, by random split without crosslinking, prevails when the cellulose and other polysaccharides are treated with ionizing radiation. Other authors reported dose rate as an important aspect. Chain scission generally dominates when polymers are irradiated in the presence of oxygen (Komolprasert, 2016). The indirect action induced by free radicals, oxygen present in air during irradiation also plays an important role for radiation efficacy. Therefore, the longer the irradiation period the greater the chance of oxygen interact and the greater the indirect effect (Magaudda, 2004).

The considerable decrease of pH paper, shown, Fig. 3, is related to the formation of acidic groups by modifying additives present during then the paper formation process. The main chemical reaction occurring in the paper degradation is acid hydrolysis, where the hemicellulose present in the paper hydrolyzes faster than cellulose. The hydrolysis can lead to a loss of fiber strength as well as links between them, affecting the mechanical properties of the paper negatively (Luner, 1969).

Through the parameter diffuse blue reflectance factor (brightness) it is possible to analyze the color of the paper, which was affected by the radiation treatment causing a yellowing of the paper packaging studied. This was probably due to the formation of chromophores groups or color centers in the cellulose (D'Almeida et al., 2009). Color induction may be partly inherent to color center formation of macromolecular materials arising from a combination of trapped radicals and permanent structural changes in the macromolecules which include conjugated chromophores (Clough, 2001). Despite of the small variation in the brightness values, after irradiation, it was possible to observe with the naked eye that the paper was yellowish.

The Fig. 3 shows that increasing the dose of radiation increases the negative influence on the analyzed properties of the packaging paper, demonstrating that the differences of given and absorbed doses can greatly influence the properties of the irradiated paper. It was also possible to note that the tearing resistance was the more sensitive property.

#### 3.2.2. Multilayer film

Radiation effects for plastic film obtained from the studied packaging were shown in Table 2.

From Table 2, there were no pinholes in non-irradiated and irradiated films. The tensile strength reductions were 1% in the longitudinal direction and 6% in the transverse direction with 25 kGy and 3% in the longitudinal direction and 2% in the transverse direction, after 50 kGy. Fengmei et al. (2000) observed that there was no significant difference in tensile strength and elongation after irradiation after 5 kGy (nylon/polyvinylidene chloride/polyethylene), while 10 kGy and 25 kGy slightly reduced mechanical properties. George et al. (2007) did not observed significantly change on the mechanical properties (tensile strength and elongation), for polypropylene polymer (PP) and others (2.5 kGy to 10 kGy). According to Demertzis et al. (1999), polyethylene (PE) is more stable to irradiation than the polypropylene polymer, due to more branched character of the polypropylene polymer chains. For polypropylene, tertiary radicals are produced, with a longer life and therefore longer time to react with oxygen and produce decomposition products containing oxygen. Furthermore, aromatic polymers such as poly (ethylene terephthalate) – Polyester (PET) or polystyrene (PS) are much more stable to gamma radiation when compared to polyolefins (PP and PE).

The results obtained for the studied packaging were shown in Table 3.

The irradiation of packaging did not change seal integrity, nonetheless, the resistance of seal, at both sides of the packaging, has undergone an insignificant change after irradiation (25 kGy and 50 kGy). When results were analyzed, they demonstrated that the packaging has undergone very little change after 25 kGy (2% negative variations on the top, 4% and 3% right hand side) on all sides of the packaging. However, these changes were higher after 50 kGy (2% top, right side by 7% and 9% left).

## 4. Conclusion

The effects of ionizing radiation on the materials, paper and multilayer plastic film, were demonstrated by the proportional increasing values on parameters according to doses. Concerning the samples of paper, obtained from the studied packaging, the main affected parameters were brightness, pH and mechanical properties: bursting strength, tearing resistance and tensile strength. The effects were proportional to dose (25 kGy, 40 kGy and 50 kGy) and yellowing of paper was also induced by radiation. In the plastic film, no pinholes were induced by radiation and the effects on the tensile strength were not significant. Although the seal packaging strength (pouches) decreased according to increasing dose, the sealing integrity was preserved.

From the studied materials cellulose fibers were the most radiation sensitive, mainly at 50 kGy. Results confirmed the importance of taking packaging systems into consideration for safety guarantees in radiation processing for healthcare products, especially for sterilization of products on large scale commercial plants.

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