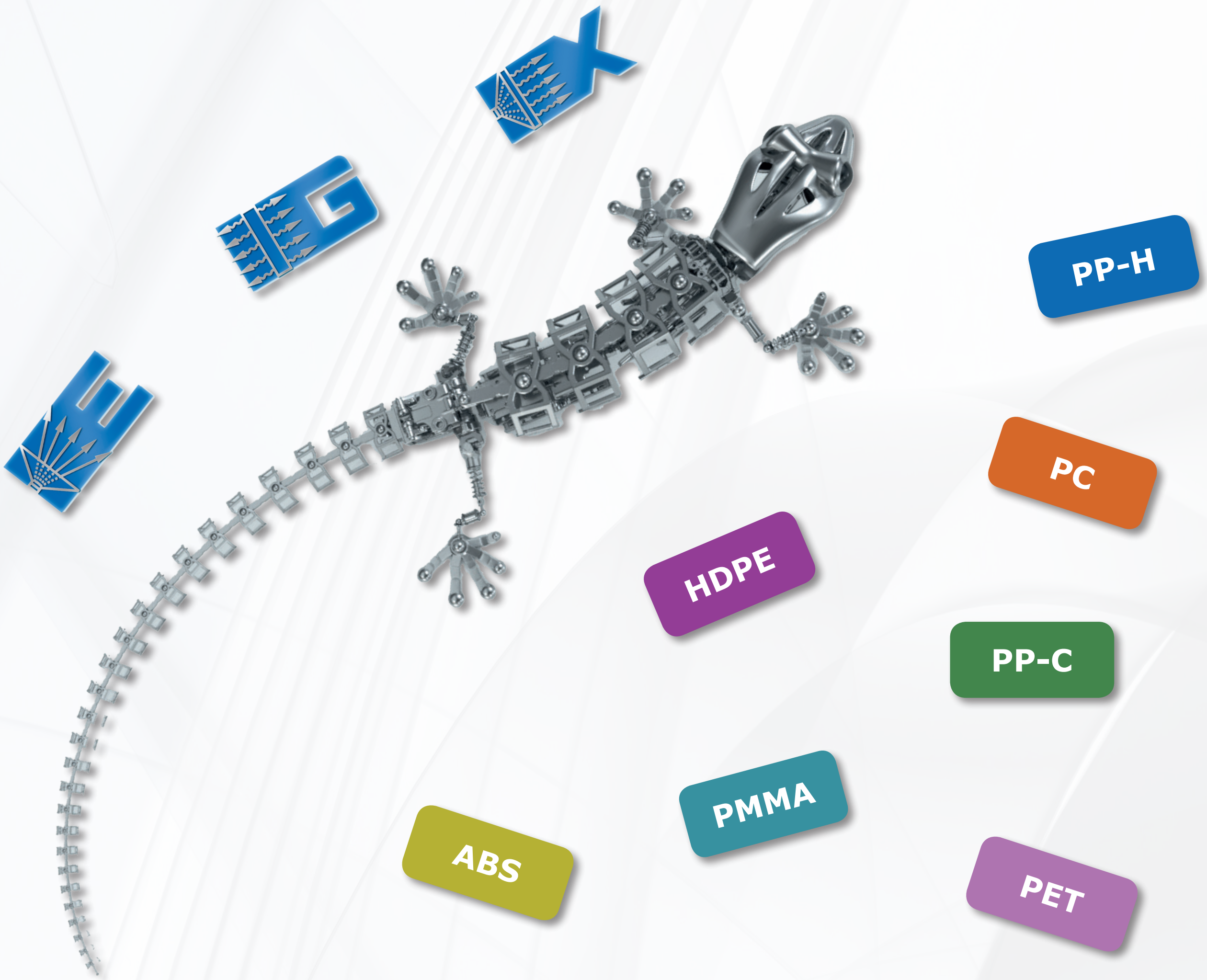
VADE MECUM

Effects of radiation type and dose on the properties of selected polymers



MEDI SCAN

Introduction

Mediscan proved anew scientific leadership in industrial irradiation by publishing a seminal research work on properties of polymers after irradiation. This work was carried out together with research partners from the University of Applied Sciences Wels and the Transfer Centre of Polymer Technology.

Ionizing radiation is widely used for sterilization of medical devices, pharmaceuticals and packaging materials for sterile goods.

As three technologies are at hand - Gamma, X-Ray and E-Beam - often the question arises which radiation type is best for a given product and what different influences have to be anticipated in dependence of the energy carrier. Particular attention was given to this subject with increased interest in X-Ray technology as substitute for Gamma irradiation.

Mediscan, as a provider of all three technologies and decades of experience in the field, was best suited to perform scientific studies together with renowned research partners.

This handout was established to support customers and regulators in predicting effects, evaluating change control measures and designing studies, when establishing irradiation as a new technology for treatment of products or changing the type of radiation within the sterilization process.

Materials and Methods

Materials chosen represent the most commonly used polymers in manufacture of medical devices. These were:

Semi-crystalline	PP-H	Polypropylene Homopolymer
	PP-C	Polypropylene Copolymer
	HDPE	High-Density Polyethylene
	PET	Polyethylene Terephthalate
Amorphous	PC	Polycarbonate
	ABS	Acrylonitrile Butadiene Styrene
	PMMA	Poly (Methyl Methacrylate)

Tests were carried out on samples of universal type 1A according to ISO 527. These specimens were irradiated in Mediscan´s facilities with precise, homogeneous doses commonly used in sterilisation of medical devices. All tests were carried out according to international standards.

Data

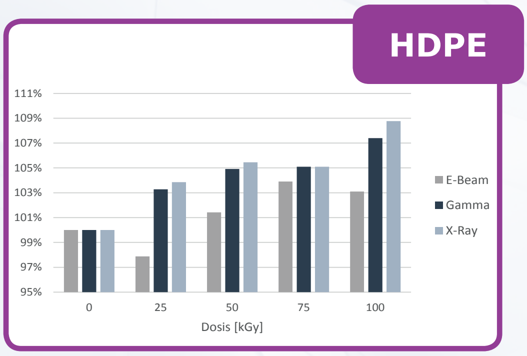
To give the clearest representation, results and behaviour of tested polymers are summarized for each test.

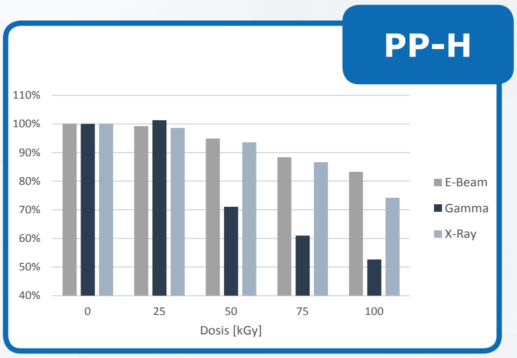
Disclaimer

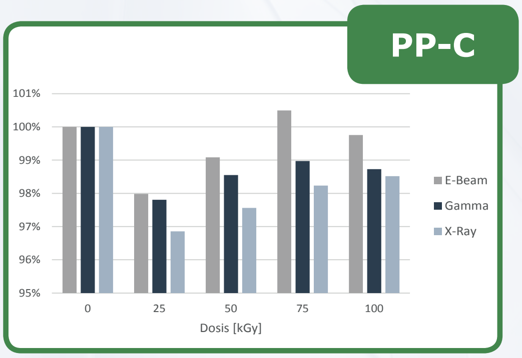
This handout is intended as information and support during product development. It does not replace any studies. Data were collected and summarized with highest level of care. However, errors can not be completely excluded. Mediscan does not take any liability for timeliness, correctness and completeness of data.

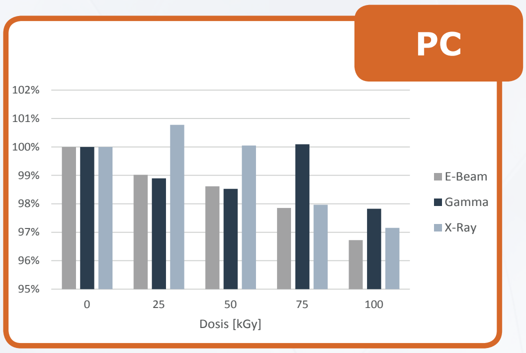
Tensile strength

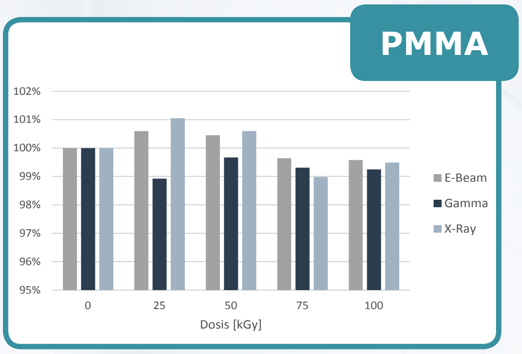
This test evaluates the maximum stress that a chosen material can withstand while being stretched or pulled before breaking and gives a good indication regarding the overall mechanical stability of a product after irradiation and thus also about continued functionality after irradiation.

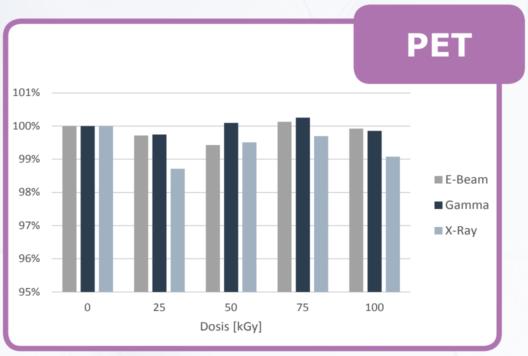


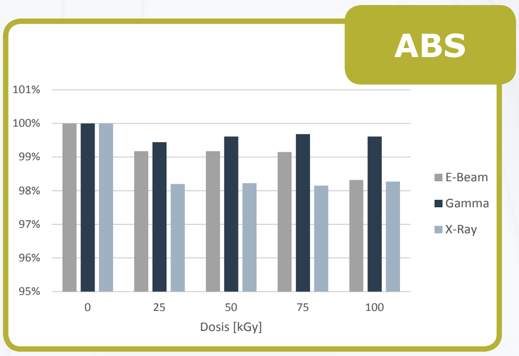








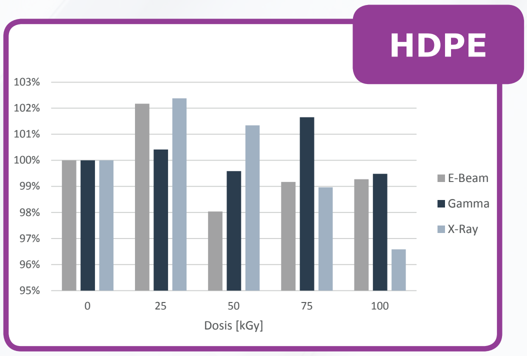


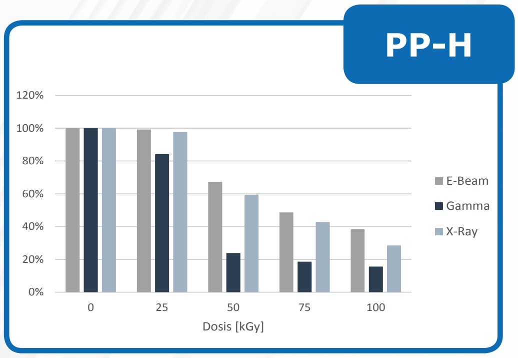


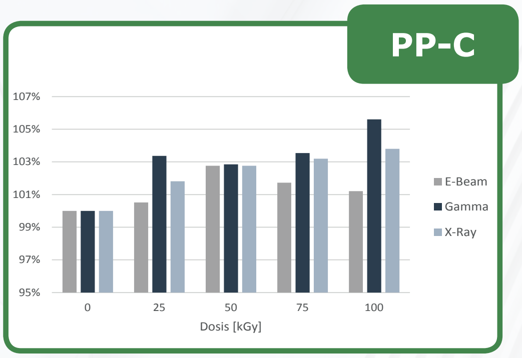
Due to crosslinking induced by ionizing radiation, an increase in tensile strength of HDPE can be observed. This effect is comparable between Gamma and X-Ray and less pronounced for E-Beam.
PP-H shows as expected a dramatic decrease for gamma irradiation. This effect is significantly lower for E-Beam and X-Ray, with endpoints at 100kGy of approx. 55% of the initial value for Gamma irradiation but 75% for X-Ray and 85% for E-Beam. Here a significant advantage for E-beam can be determined.
PPC shows a very constant behaviour and high stability for all three radiation technologies up to 100kGy. Based on this parameter there are significant advantages in the use of a copolymer versus a homopolymer.
PC, PMMA, PET and ABS are not significantly influenced by either technology.

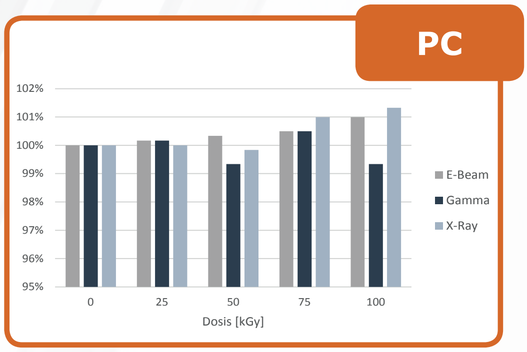
Yield Strain

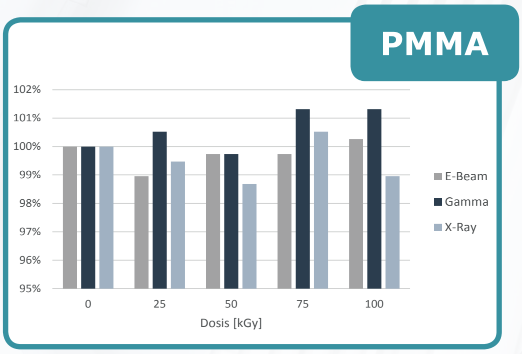
The yield point indicates the border between elastic behaviour where a material deforms elastically and returns to its original shape and the beginning of plastic behaviour with irreversible deformation. This parameter gives a good indication for continued functionality after irradiation of a product.

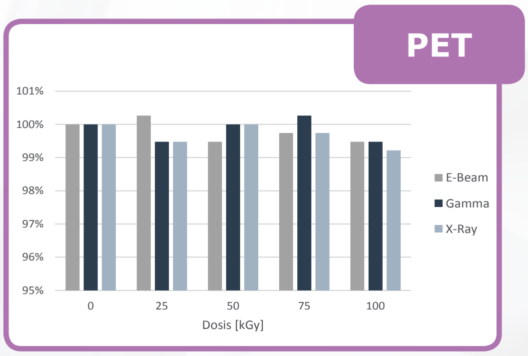


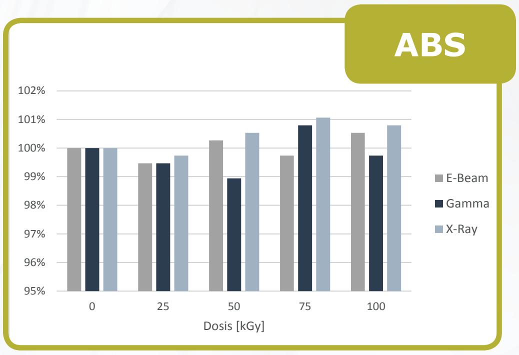








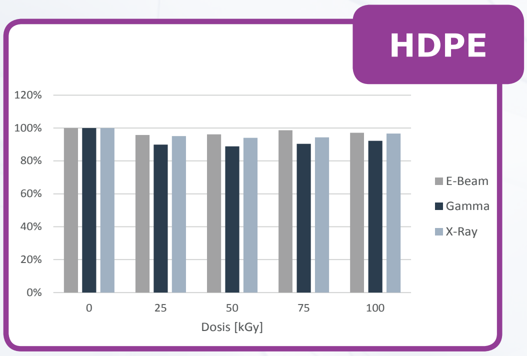


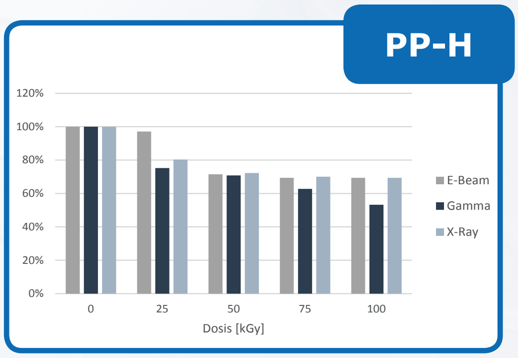


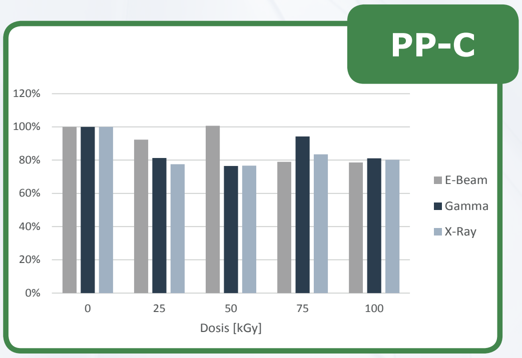
While HDPE shows only slight variations for all technologies, PP-H shows a significant decrease, most pronounced with Gamma irradiation, in contrast to PP-C, where even a very slight increase can be observed.
As with tensile strength, PC, PMMA, PET and ABS show no change with applied dose, independent of the employed technology.

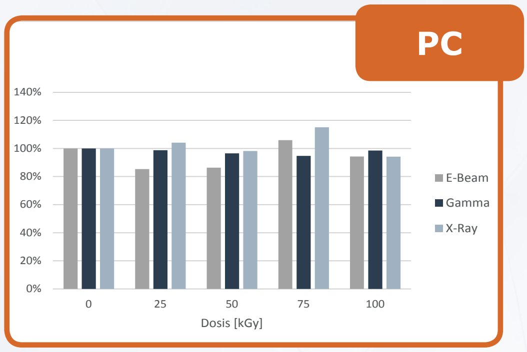
Notched Charpy impact strength

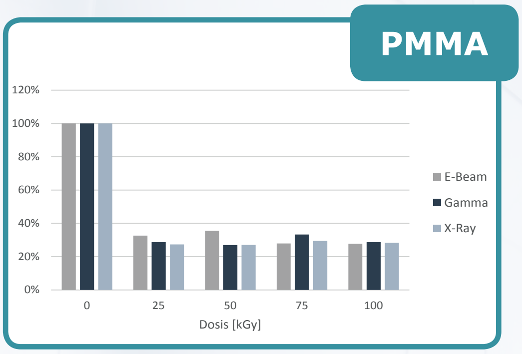
In this test the amount of energy absorbed by a material during fracture is determined. The absorbed energy is a measure for the toughness of a given material and therefore robustness of a product.

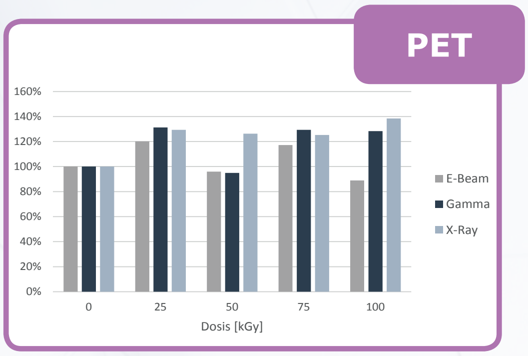


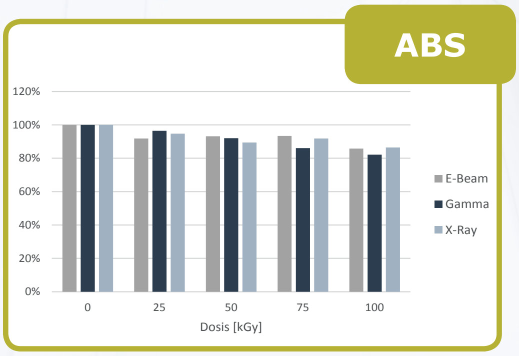








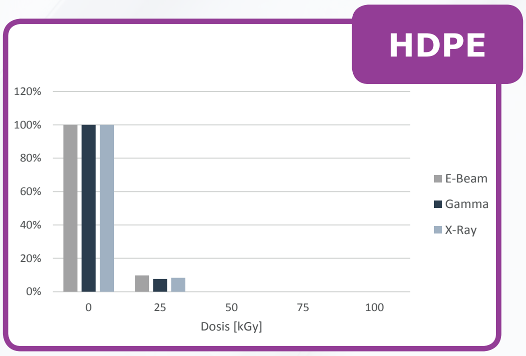


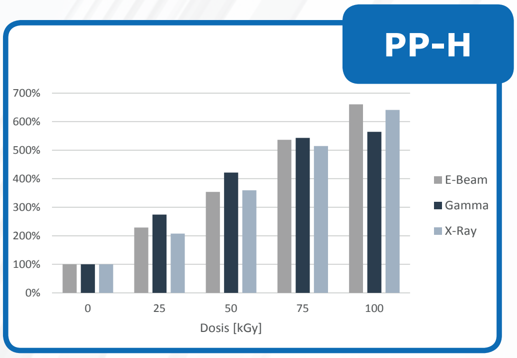


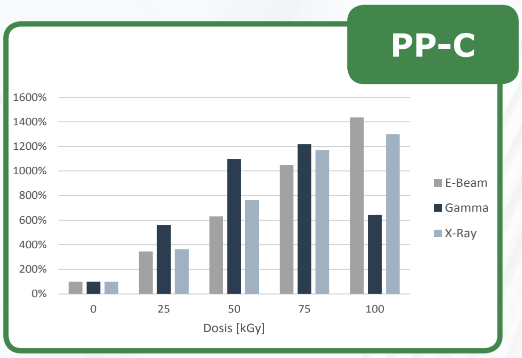
HDPE shows a very slight decrease at the lowest dose level and afterwards constant values for all technologies. For PP-H the values decrease immediately by approximately 30% and stay constant for higher doses. PP-C shows a behaviour similar to HDPE. PC shows mostly constant values independent of the applied dose, while ABS suffers a slight decrease in stability, PET shows an actual increase in the measured values. PMMA strikingly and independent of the type of radiation used, exhibits a pronounced decrease at the lowest dose step, but thereafter values stay constant.

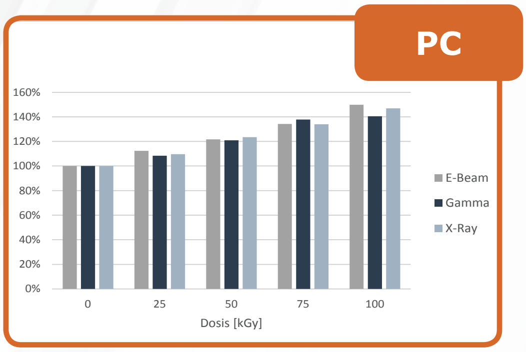
Melt flow rate (MFR)

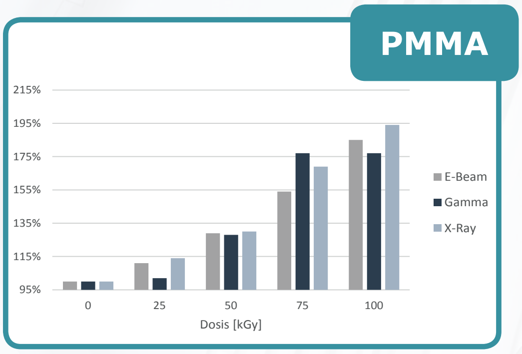
This parameter is usually used to define raw material and characteristics for its intended use. However, it also gives a good indication for the cleavage of polymer chains and a resulting mechanical instability or for crosslinking of the material.

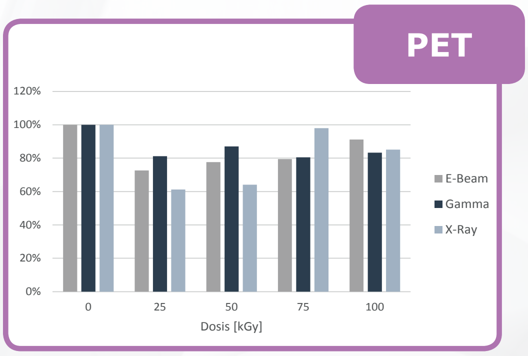


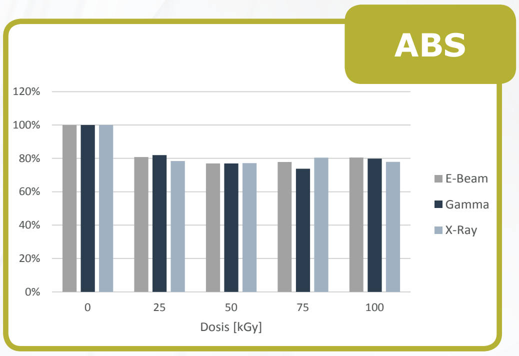








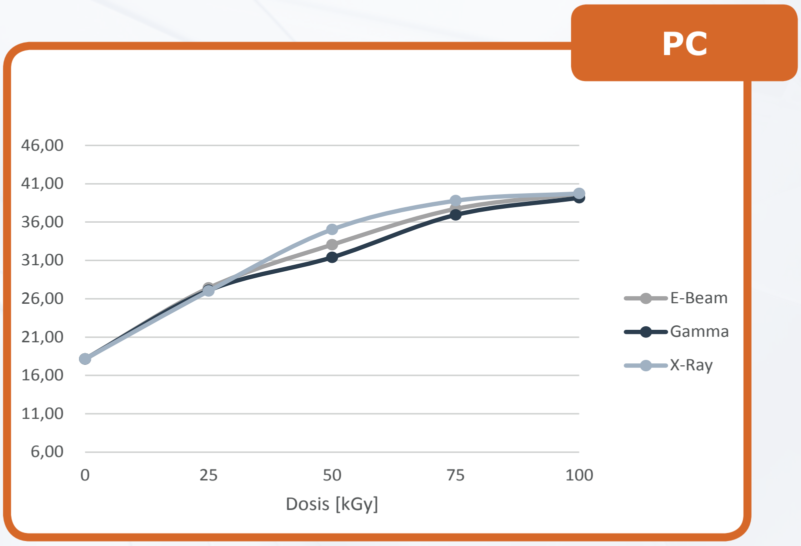


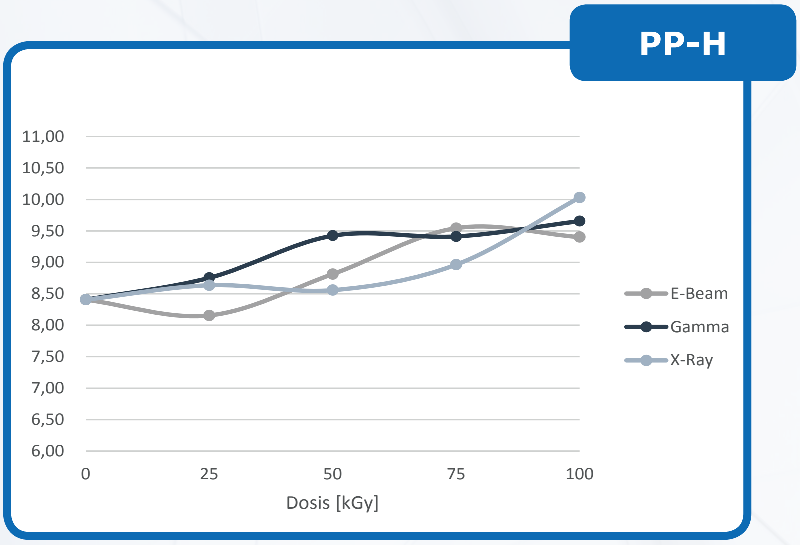


Due to cross linking effects the MFR for HDPE drops significantly and is already at 50kGy below the limit of measurement. PP-H and PP-C on the other hand show a significant increase with the applied dose, indicating a pronounced cleavage of the chains. It is interestingly to note, that when using gamma irradiation the trend for PP-C is more pronounced at 50kGy and reversed at 100kGy. PC shows a slight increase while PMMA reacts with a pronounced increase of the MFR. PET and ABS show a decrease for small dose values which remain constant wehen increasing the dose. In these cases, there is no noticeable dependency on the type of radiation.

Colouration

Colouration is a known effect of radiation on a variety of plastics and often used as an argument against irradiation as sterilization means, although colouration in itself does not give any indication for decrease performance of a polymer based product nor for a lower mechanical stability.



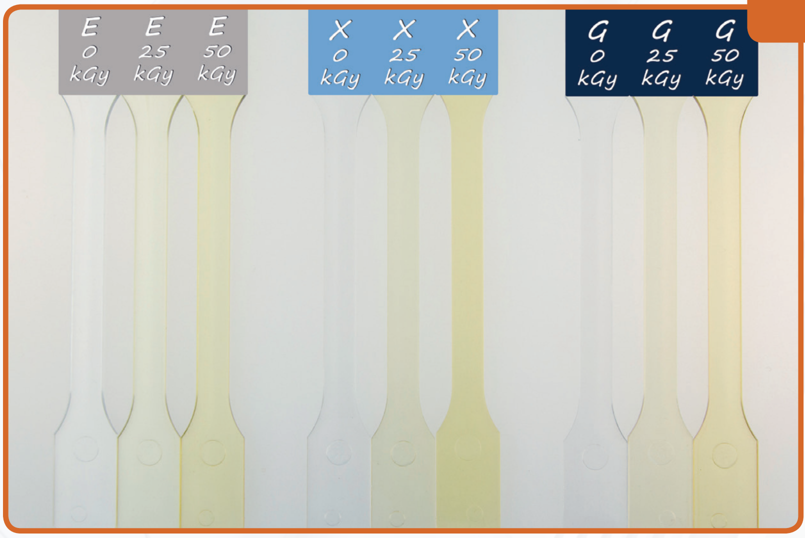


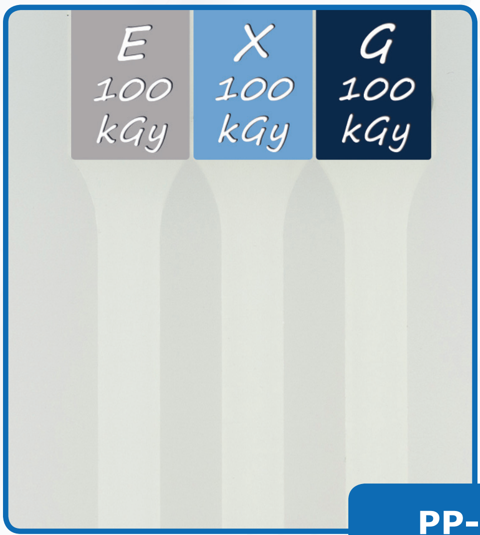
As can be seen from the example of Polypropylene Homopolymer on the one hand with only very slight coloration and Polycarbonate with a pronounced colour formation, this effect – for this specific case - is converse to the mechanical stability of the polymers, where PC shows generally a higher stability than PP-H.

Colouration

Colouration is dose dependant, an effect which is used when employing PMMA dosimeters for measuring the applied dose. However, overall no differences can be seen between the three different radiation technologies. Generally, it can be concluded, that with higher dose homogeneity of a process less pronounced differences in coloration between individual products can be observed.

PC





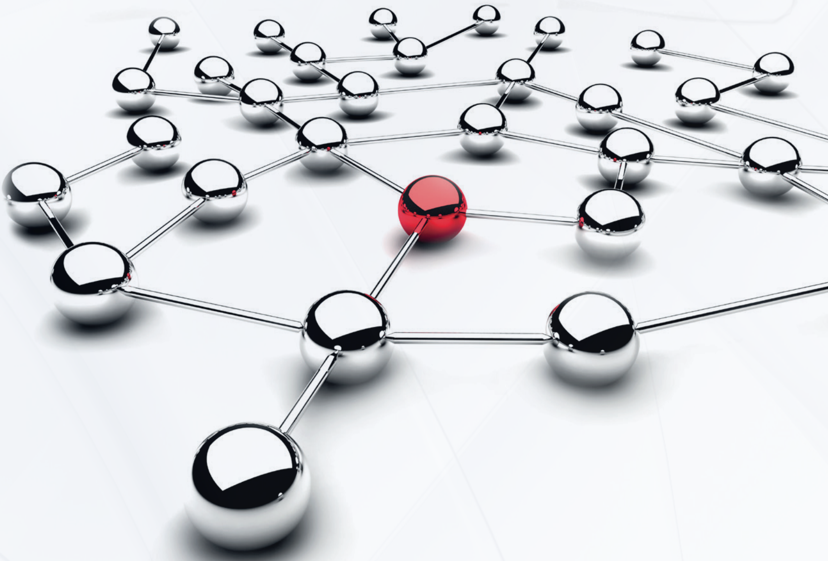
PP-H

The above photos clearly demonstrate the dose dependency of the pronounced colouration for PC and the negligible effects on PP-H as well as the fact that no significant differences in development of discolouration between the three different technologies can be observed.

Summary of results

All obtained data give secured evidence that irradiation technologies induce comparable effects in the treated samples. A major concern that X-Ray treatment might be more damaging than Gamma sterilization could be rebutted. On the contrary, both technologies with higher dose rate (E-Beam and X-Ray) proved more gentle to polymers than Gamma in many aspects. However, care has to be taken regarding the aspect of maximum dose applied to the product. Usually E-Beam treatment shows a higher DUR (Dose Uniformity Ratio) resulting in a significant higher maximum applied dose to product than would be seen in a gamma tote irradiator, and slightly higher than in a gamma pallet irradiator. In some cases this might be of disadvantage for E-Beam treatment but in other cases as seen for example with tensile strength for PP-H, the advantage of the E-Beam treatment versus Gamma treatment is never compensated by the DUR advantage of Gamma.

Citation: Burgstaller C, Höftberger T, Gallnböck-Wagner B, Stadlbauer W. Effects of radiation type and dose on the properties of selected polymers.
Polym Eng Sci. 2020;1–16.



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