Radiation as Sterilization Modality of Intravenous Fluid Delivery System Device and its Effects on the Physicochemical and Functional Properties

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ABSTRACT

Due to the growing demands for medical device supplies in the world today, more effective, and efficient techniques for sterilization are currently being evaluated. Sterilization based on ionizing radiation is a widely used method globally for reducing disease-causing microorganisms in healthcare products. Currently, the Philippines is entering the market for radiation sterilization as the upgrading of its irradiation facilities to cater to commercial-scale demands is coming to completion.

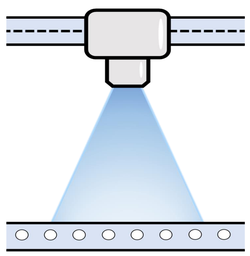
To aid in this endeavor, a case study on a locally produced single-use intravenous (IV) fluid delivery system was conducted. The impact of electron beam (EB) irradiation on the physicochemical (FT-IR, TGA) and functional properties (JIS T 3211-2011) of the medical device at different absorbed doses were assessed.

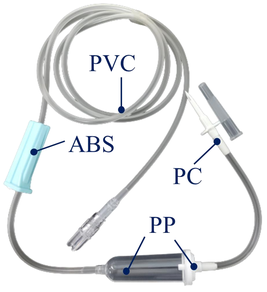
The results of the characterizations indicate that at absorbed doses of 15 kGy and 25 kGy, most of the physicochemical properties were not affected while functional properties conformed with industrial criteria and standard. The most obvious effect of irradiation was the discoloration of some parts of the device. The suitability of EB as sterilization modality was assessed based on ISO 11137-2:2016. Aerobic Plate Count and Mold and Yeast Count analyses showed 0 cfu/g average bioburden. Using the VDmax method, all samples passed the sterility test and substantiated 15 kGy as the potential radiation sterilization dose.

INTRODUCTION

ELECTRON BEAM STERILIZATION

- Machine generated (accelerator)
- Fast (High dose rate)
- "Cold" Process
- High throughput process
- Kills effectively disease-causing organisms; suitable as post-sterilization of medical devices.





- An IV fluid delivery system is used for controlled infusion of medicines over an extended period.
- It is made up of distinct polymers polyvinyl chloride, polypropylene, acrylonitrile butadiene styrene, polycarbonate

METHODOLOGY

1. RADIATION PROCESSING

- IV fluid delivery system samples (infusion sets) were irradiated with electron beam at doses 15, 25, 35, 50, and 80 kGy.
- A semi-commercial electron beam irradiator was used to apply 2.0 MeV and 14.1 mA current to the samples.

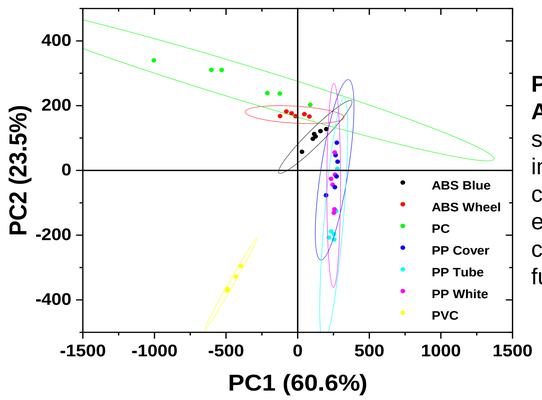
2. CHARACTERIZATIONS

- **Fourier Transform-Infrared (FT-IR) Spectroscopy** and **Thermogravimetric Analysis (TGA)** were used for the assessment of the physicochemical properties of the infusion sets before and after irradiation.
- All functional properties were tested according to the **Japanese Industrial Standard (JIS) T 3211-2011.**

3. ESTABLISHMENT OF RADIATION STERILIZATION DOSE

- The radiation sterilization dose was established based on the ISO 11137-2:2016, supplemented by the characterization results..

RESULTS & DISCUSSION



Principal Component Analysis (PCA) of the FT-IR spectra of irradiated samples indicated no significant changes in the structure of each of the polymer components of the device as a function of dose.

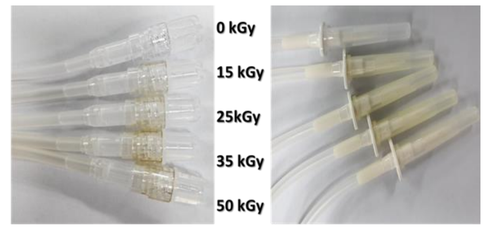
Thermogravimetric Analysis indicated that mass changes from the temperature range 30 – 100°C (working temperature) were very minimal indicating that radiation dose up to 80 kGy did not have adverse effect on the physical integrity of the infusion set samples.

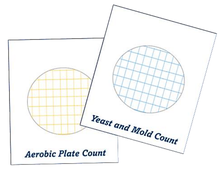
% Weight Change				
Sample	Polycarbonate	Polypropylene	Acrylonitrile Butadiene Styrene	Polyvinyl Chloride
Control	0.05	0.46	0.24	0.01
15 kGy	0.72	0.70	0.33	0.42
25 kGy	0.13	0.76	0.48	0.80
35 kGy	0.47	0.07	0.29	0.51
50 kGy	0.32	0.69	0.02	0.27
80 kGy	0.42	0.48	0.12	1.41

Japanese Industrial Standard T 3211 – 2011				
TEST	CRITERIA	DATA (for all samples)	REMARKS	DECISION
Dimension (mm) Upper Tube	114 – 226	118 – 123	Dimension is within the range.	✓
Dimension (mm) Lower	1140 – 2260	1177 – 1190	Dimension is within the range.	✓
Air Tight (Leak Test)			No bubbling/leakage observed.	✓
Air Flow (Clog Test)			Bubbling in samples was observed.	✓
Adjusting Gear Test			Gear worked properly as observed in the bubbling	✓
Fluid Flow (mL)	225 – 275	247 – 258		✓

- All irradiated infusion sets passed the criteria set by the **JIS T 3211-2011 after testing.**
- The infusion set samples can function properly even after irradiation at any dose of electron beam, from 15 kGy to 80 kGy.

- Radiation-induced discoloration was prominent in the polycarbonate and polyvinyl chloride parts.
- This is a major concern since color is an important quality of medical devices as it communicates safety and cleanliness to consumers..





- Sterilization dose was established using ISO 11137-2:2016.
- Bioburden was employed to count the viable microorganisms present in the samples.
- **The average bioburden of 3 batches of 10 replicates was 0 CFU/g.**

- Since bioburden was 0 CFU/g, 15 kGy, which had minimal effect on color and other properties, was pre-selected as the sterilization dose
- **VD_{max}^{15} method was used to validate and to substantiate 15 kGy.**

- Sterility testing of infusion sets (SIP = 1; VD_{max}^{15} = 0.0 kGy) gave 1 out of 10 turning positive for microbial growth.
- Based on the **VD_{max}^{15} method, the samples passed the sterility test and 15 kGy was verified and substantiated.**

CONCLUSION

- Electron beam radiation induced minimal effect on the physicochemical and functional properties of the infusion set device from 15-80 kGy.
- Discoloration was prominent in polycarbonate and polyvinyl chloride components of the device giving concern on the device aesthetic.
- The use of electron beam as sterilization modality for the infusion set devices showed feasibility at 15 kGy.

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