

# Radiation sterilization of medical equipment, personal protection equipment, and the other microbiologically infected objects

Andrzej Rafalski

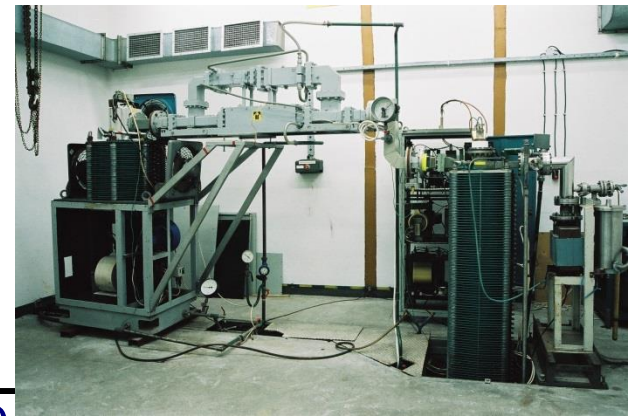
Centre of the Radiation Chemistry and Technology  
Institute of Nuclear Chemistry and Technology  
Warsaw, Poland

7 October 2020

Radiation Sterilization Plant  
is situated  
at the Institute of Nuclear  
Chemistry and Technology  
in Warsaw

The activity was sponsored in the frame of the Central European Initiative  
(CEI) Extraordinary Action 2020

# STERILIZATION FACILITY AT INCT, WARSAW, POLAND



**Elektronika 10/10**

<b>ACCELERATOR</b> <ul style="list-style-type: none"><li>• electron energy</li><li>• beam power</li><li>• scan width</li><li>• AC power consumption</li></ul>	Elektronika 10/10 10 MeV 15 kW 65 cm 120 kVA
<b>BUILDING</b> <ul style="list-style-type: none"><li>• total surface</li><li>• total capacity</li><li>• storage surface</li></ul>	1814 m <sup>2</sup> 9230 m <sup>3</sup> 2x288 m <sup>2</sup>
<b>PROCESS PARAMETERS</b> <ul style="list-style-type: none"><li>• conveyor speed</li><li>• productivity</li><li>• unit size</li></ul>	0.3 - 7 m/min. 10 000 kg kGy/h 58x46x(10-20) cm; 0.05 m <sup>3</sup>

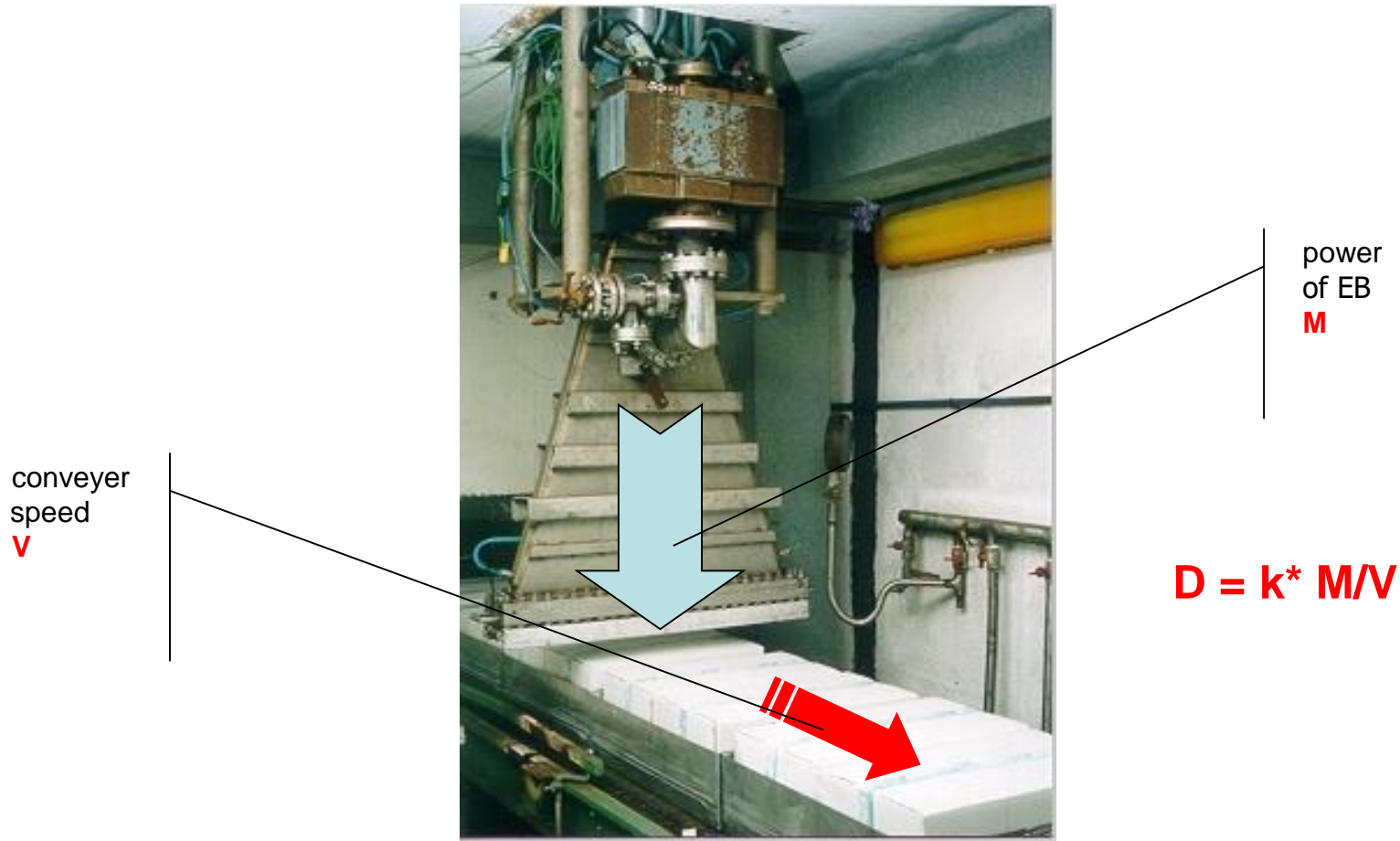
The activity was sponsored in the frame of the Central European Initiative (CEI)  
Extraordinary Action 2020



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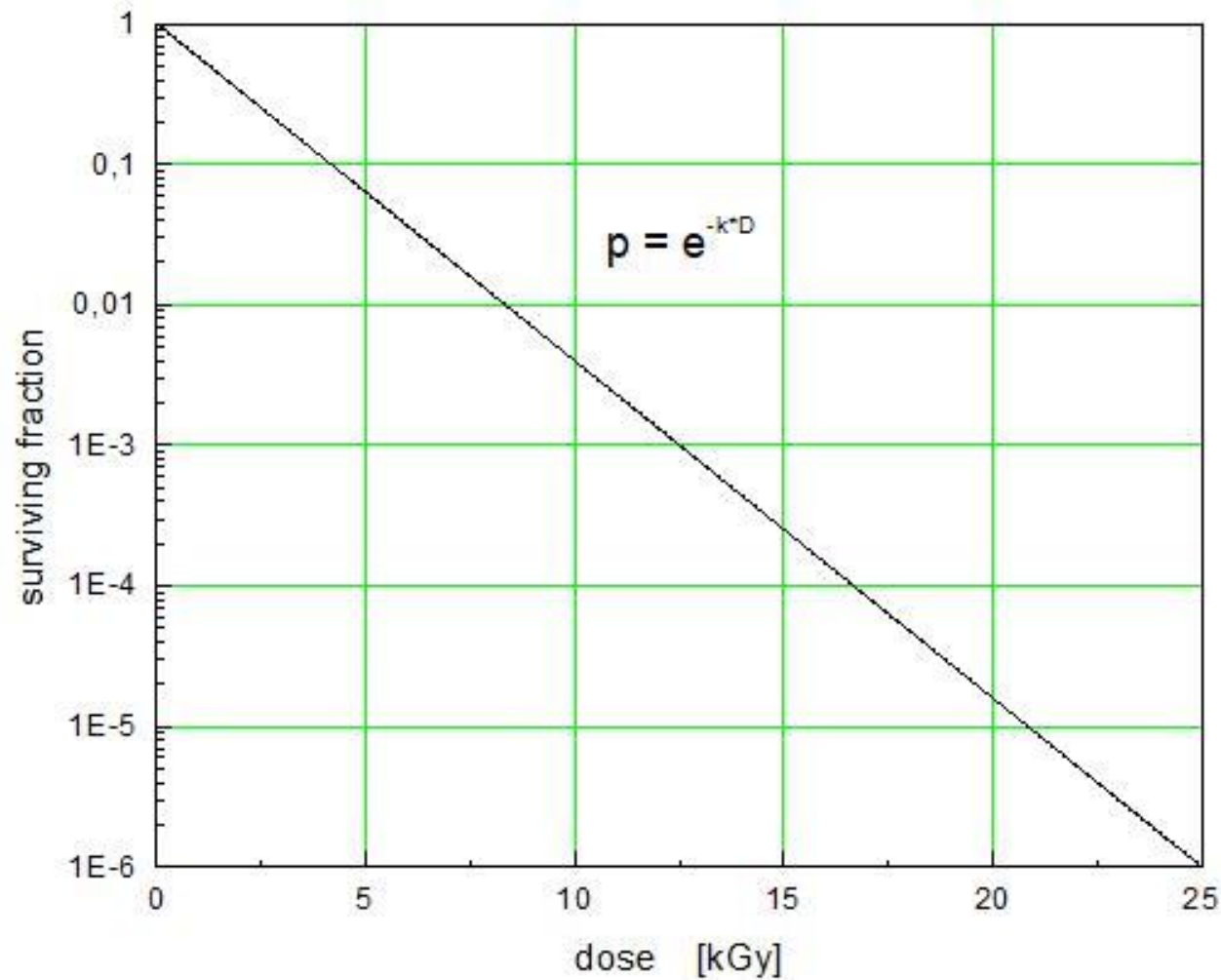


We regulate the dose by changing the conveyer speed.



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## Surviving fraction of bacteria vs dose



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# Irradiation Sterilized Medical Disposable Products:

Syringes

Absorbents

Catheters

Gloves

Drains

Surgical gowns

Tubing

Hand towels

Urine bags

Beakers and lab ware

Drain pouches

Petri dishes

Bandages

Culture tubes

Hydrogels

Personal protection equipment

Bottles for eye drops

CERTIFICATE No. GIF-IW-400/0012\_01\_01/04/111/15

*Main Pharmaceutical Inspector***CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER****Part 1**

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended

**Main Pharmaceutical Inspector***/the Competent Authority of Poland/*

confirms the following:

the manufacturer

**Instytut Chemii i Techniki Jądrowej**  
**16 Dorodna Street, 03-195 Warszawa, POLAND**

site address

**Instytut Chemii i Techniki Jądrowej**  
**16 Dorodna Street, 03-195 Warszawa, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **GIF-IW-400/0012/01/779/ZW306/14** in accordance with Art. 40 of Directive 2001/83/EC transposed in pharmaceutical law of 6<sup>th</sup> of September 2001 (Dz. U. z 2008 r. Nr 45, poz. 271, z późn. zm.).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **23-25/06/2015**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.



date: 2015 -09- 2 1

Main Pharmaceutical Inspectorate  
12 Senatorska Street, 00-082 Warsaw, Poland  
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

  
Zofia Ulz  
Main Pharmaceutical Inspector

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Transplants irradiated in the Radiation Sterilization Plant  
in the years 2010 - 2012.

Institution	2010	2011	2012
Krajowe Centrum Bankowania Tkanek i Komórek, WUM	977	1729	1618
Regionalne Centrum Krwiodawstwa i Krwiolecznictwa, Katowice	6319	8012	6476
Regionalne Centrum Krwiodawstwa i Krwiolecznictwa, Kielce-Morawica	4430	3260	2880
Centrum Leczenia Oparzeń, Siemianowice	1013	576	630
Total	12 739	13 577	11 604

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**Thank you for your**

**attention!**