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COVID-19 Pandemic: Radiation Sterilization of PPE

(personal protective equipment)

Thursday, May 21, 2020, 14.00 – 15.30 CET

Welcome!

Melissa Denecke - IAEA

Melissa Denecke is the **Director of the Division of Physical and Chemical Sciences in the Department of Nuclear Sciences and Applications at the International Atomic Energy Agency in Vienna**.

She is a radiochemist and an internationally recognised expert in application of state-of-the-art techniques for radionuclide characterisation on a molecular scale using a number of laser- & accelerator-based and research reactor techniques.

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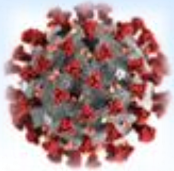
Chair - Panelist

Celina HORAK, IAEA

Celina Horak is **Radiation Processing Specialist** at the Radioisotope Products and Radiation Technology Section from the Division of Physical and Chemical Sciences at the International Atomic Energy Agency (IAEA)

She is Microbiologist, Biotechnologist and Food Industrial Technologist and had more than 30 years of experience on the field of Radiation Processing for Health Care, Food and Agriculture, Environment and Industrial applications. Before joining IAEA in August 2019, she was the Manager of the Radiation Science and Technology Centre in CNEA, Argentina, and professor in the Nuclear Engineering Program and Nuclear Application Specialization at the Institute Beninson.

Webinar Outline



1. Current status of radiation sterilization of PPE worldwide.

2. PPE reprocessing techniques

3. Reprocessing test of respiratory masks by radiation: issues and challenges

- Some experience from RoK, Israel, France, Poland and USA

4. Prospectus on sterilisation of other PPEs

- Brazil experience on sanitization of hand-made masks
- Philippines sterilisation of different kind of PPE and 3D-printed venturi valves
- IIA: An Industrial Processing Perspective

5. Closing

6. Q&A Session

Speakers

Melisa DENECKE
NAPC Director

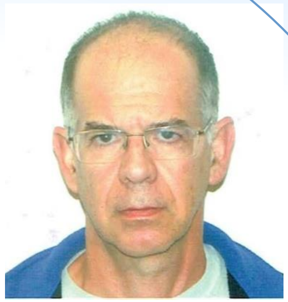
Celina HORAK
Rad-Processing
Specialist

1. Introduction and current Status IAEA

Philippe CINQUIN
France

2. PPE reprocessing techniques

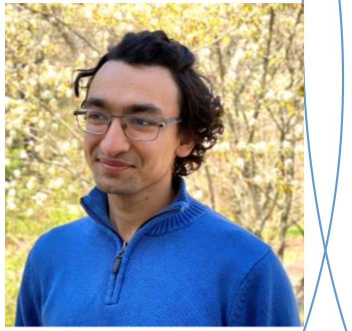
Byungnam KIM
R. of Korea



Elazar SARID
Israel

Laurent CORTELLA
France

Piotr ULANSKI
Poland



Avilash CRAMER
USA

3. Reprocessing test of respiratory masks by radiation: issues and challenges

Luvimina LANUZA
Phillipines

Pablo VAZQUEZ
Brazil

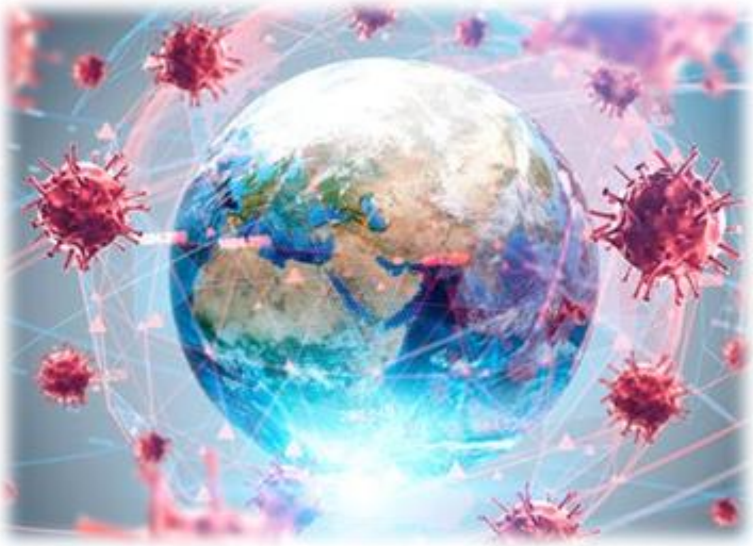
Paul WYNNE
IIA

4. Prospectus on sterilisation of other PPEs

IAEA - NAPC response in the pandemia

Covid-19 → **PPE-Shortage**

Further actions



To find out if radiation technologies, electron beam (EB) and gamma irradiation, can be used for (re)sterilization and/or disinfection of PPE with no detrimental changes to its structure and functionality features

To assess about National/Regional Regulation (transitory approvals were released)

→ **Technical report:**

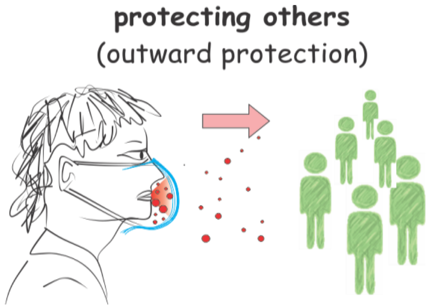
STERILIZATION AND REPROCESSING OF PERSONAL PROTECTIVE EQUIPMENT (PPE), INCLUDING RESPIRATORY MASKS, BY IONIZING RADIATION
http://www-naweb.iaea.org/napc/iachem/working_materials/Technical%20Report%20(Mask%20Reprocessing).pdf

→ **Survey** Irradiation facilities irradiating PPE/conducting research on…

→ **Webinar** to present the last findings and give some guidance

The need of PPE (sterile or reprocessed personal protective equipment)

Face masks and irradiation

Respiratory mask	Surgical mask	Home-made mask
		
Reduces wearer's exposure to particles including small particle aerosols and large droplets  	Fluid resistant, provide the wearer protection against large droplets. Protect others from the wearer's respiratory emissions.  	Use of Cloth Face Coverings Help Slow the Spread of COVID-19 
Evaluated, tested, and approved by National authorities	Cleared by Health National Authorities	N/A
Reprocessing (Disinfection dose)	Sterilization/disinfection dose	Disinfection dose

Sterilization by Radiation

ISO 11137-1, gives the guidance for the irradiation process validation and routine control

Sterilization (ISO 11137-2; ISO/TS 134003)

Inactivation approaches high/medium level disinfection

Dmín

Objective not reached

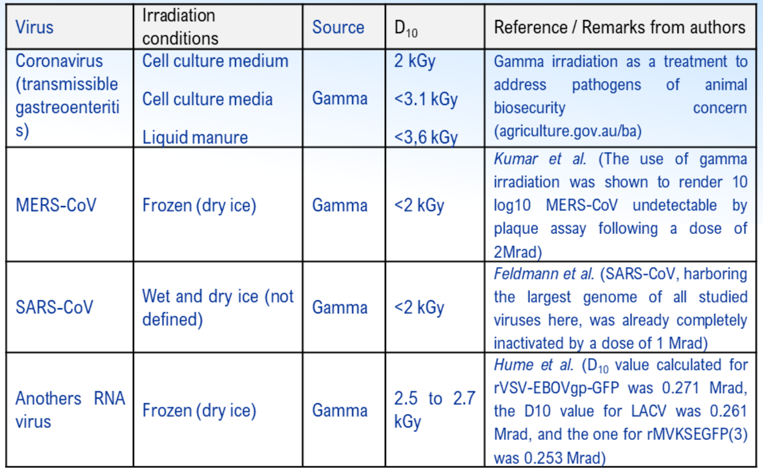
Objective reached

Acceptable quality

Mofified quality

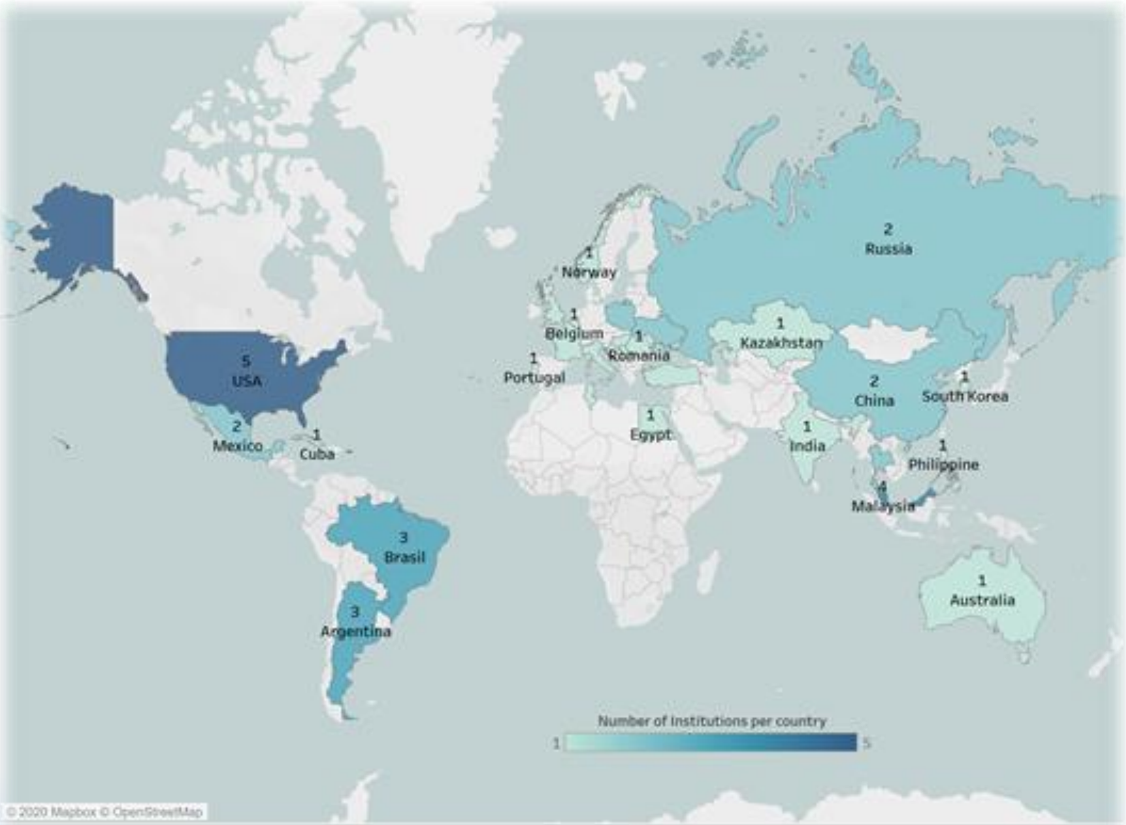
Dmax

Compatibility, Functionality and Stability Studies (morphological, thermal and chemical properties; functionality performance)



Virus	Irradiation conditions	Source	D_{10}	Reference / Remarks from authors
Coronavirus (transmissible gastreoenteritis)	Cell culture medium Cell culture media Liquid manure	Gamma	2 kGy <3.1 kGy <3,6 kGy	Gamma irradiation as a treatment to address pathogens of animal biosecurity concern (agriculture.gov.au/ba)
MERS-CoV	Frozen (dry ice)	Gamma	<2 kGy	*Kumar et al.* (The use of gamma irradiation was shown to render 10 log10 MERS-CoV undetectable by plaque assay following a dose of 2Mrad)
SARS-CoV	Wet and dry ice (not defined)	Gamma	<2 kGy	*Feldmann et al.* (SARS-CoV, harboring the largest genome of all studied viruses here, was already completely inactivated by a dose of 1 Mrad)
Anothers RNA virus	Frozen (dry ice)	Gamma	2.5 to 2.7 kGy	*Hume et al.* (D_{10} value calculated for rVSV-EBOVgp-GFP was 0.271 Mrad, the D10 value for LACV was 0.261 Mrad, and the one for rMVKSEGFP(3) was 0.253 Mrad)

Survey:

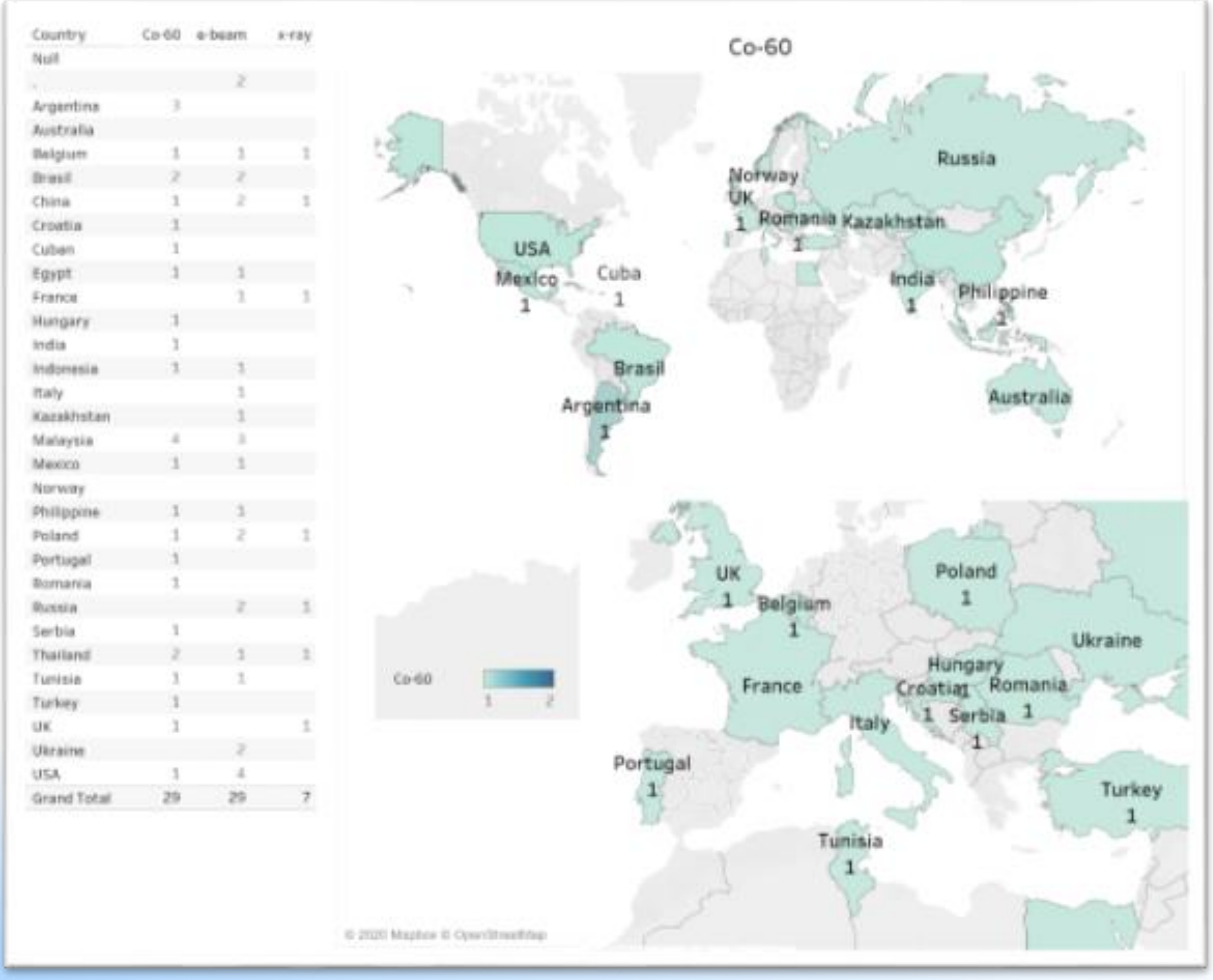


Survey questionnaire

- What kind of **items** do you **usually irradiate** (health care products, pharmaceuticals, labware, packaging, raw materials, etc) and how **did it change** since the beginning of the pandemic?
- Which **irradiation mode** (gamma from cobalt-60, e-beam, x-ray) are you using?
- Do you **sterilize new or used PPE**? If so, could you please specify the types of PPE?
- Do you have to apply **extra safety measures** for operating your facility during these times?
- Are you doing any **research studies related to COVID-19**?

Survey:

Radiation Technologies: Gamma, E-Beam and X- rays

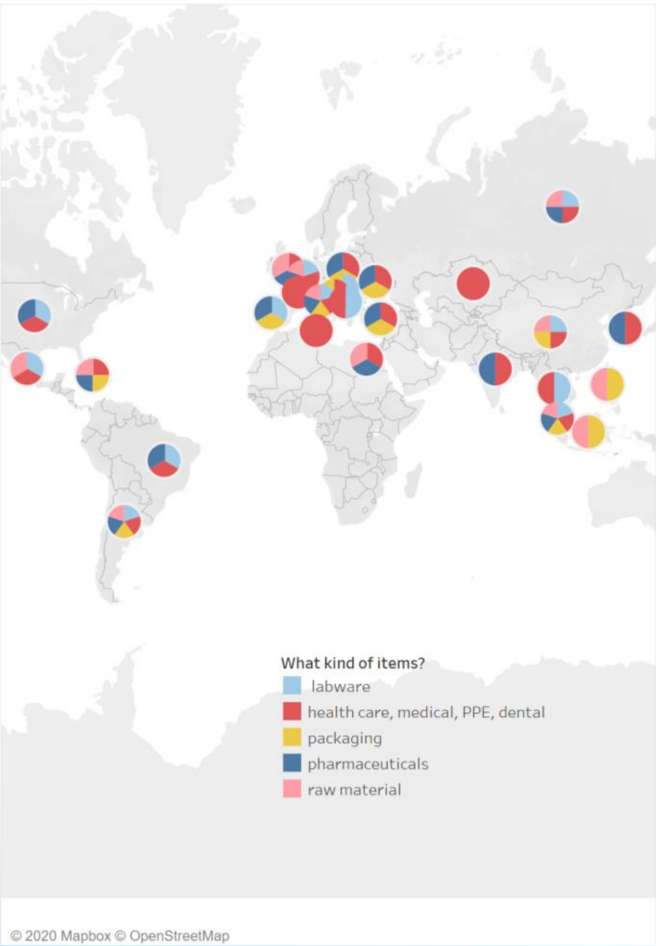


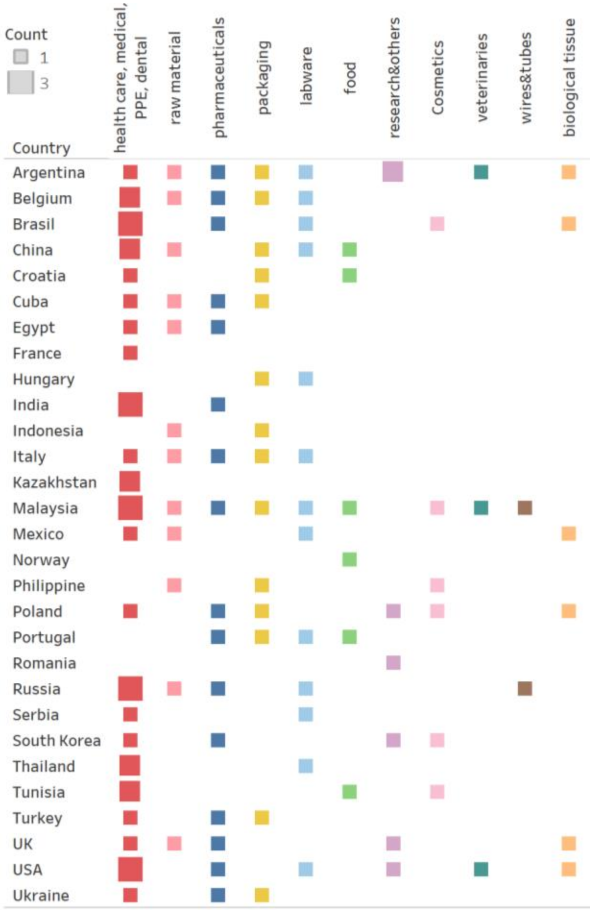
Country	Co-60	e-beam	x-ray
Null			
.		2	
Argentina	3		
Australia			
Belgium	1	1	1
Brasil	2	2	
China	1	2	1
Croatia	1		
Cuban	1		
Egypt	1	1	
France		1	1
Hungary	1		
India	1		
Indonesia	1	1	
Italy		1	
Kazakhstan		1	
Malaysia	4	3	
Mexico	1	1	
Norway			
Philippine	1	1	
Poland	1	2	1
Portugal	1		
Romania	1		
Russia		2	1
Serbia	1		
Thailand	2	1	1
Tunisia	1	1	
Turkey	1		
UK	1		1
Ukraine		2	
USA	1	4	
Grand Total	29	29	7

Survey:

Irradiation item categories

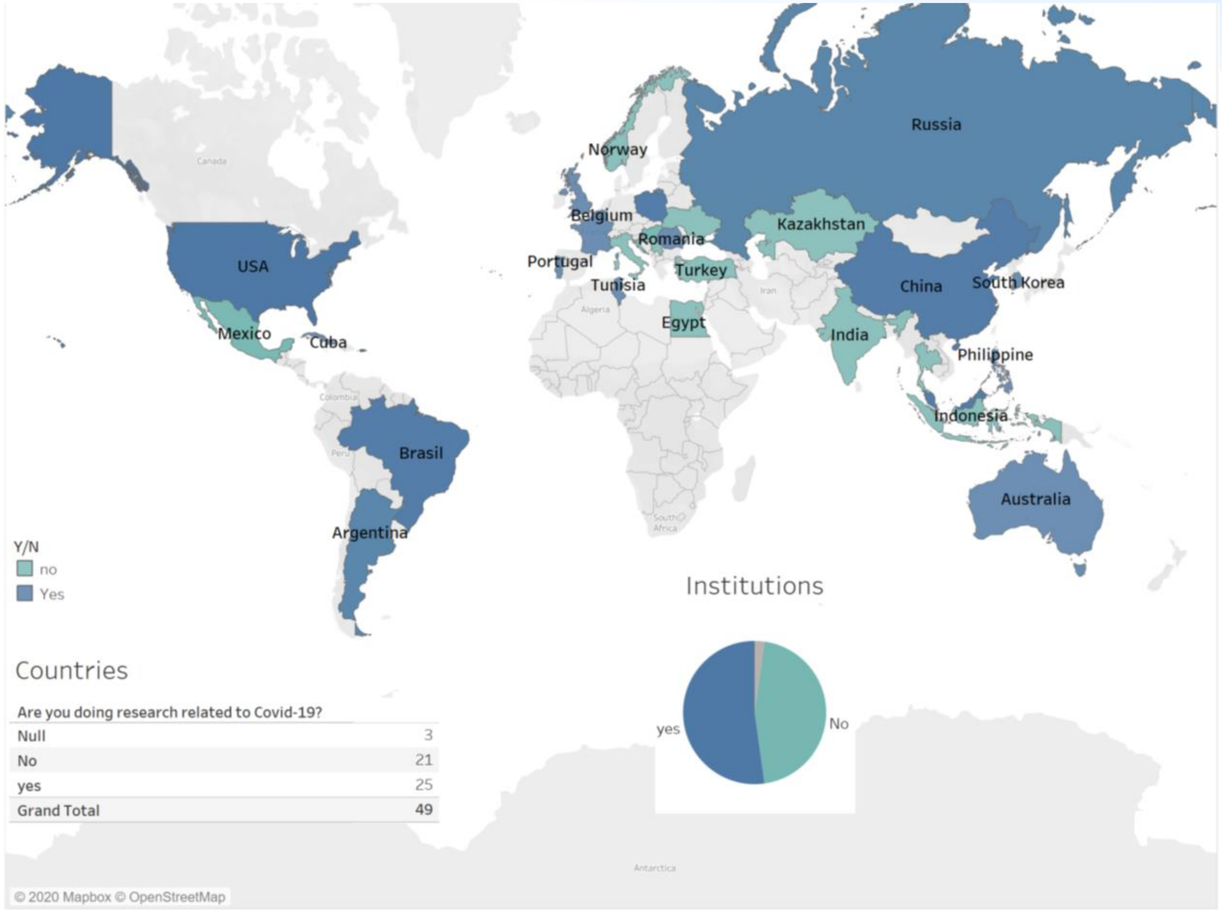
Main Categories





Country	health care, medical, PPE, dental	raw material	pharmaceuticals	packaging	labware	food	research&others	Cosmetics	veterinaries	wires&tubes	biological tissue
Argentina	■	■	■	■	■		■		■		■
Belgium	■	■	■	■	■						
Brasil	■		■		■			■			■
China	■	■		■	■	■					
Croatia	■			■		■					
Cuba	■	■	■	■							
Egypt	■	■	■								
France	■										
Hungary				■	■						
India	■		■								
Indonesia		■		■							
Italy	■	■	■	■	■						
Kazakhstan	■										
Malaysia	■	■	■	■	■	■		■	■	■	
Mexico	■	■			■						■
Norway						■					
Philippine		■		■				■			
Poland	■		■	■			■	■			■
Portugal			■	■	■	■					
Romania							■				
Russia	■	■	■		■					■	
Serbia	■				■						
South Korea	■		■				■	■			
Thailand	■				■						
Tunisia	■					■		■			
Turkey	■		■	■							
UK	■	■	■				■				■
USA	■		■		■		■		■		■
Ukraine	■		■	■							

Research related to COVID-19 with irradiation



Countries

Are you doing research related to Covid-19?	
Null	3
No	21
yes	25
Grand Total	49

Panelist

Philippe CINQUIN

CNRS / Univ. Grenoble Alpes / Grenoble University Hospital

Pr Philippe Cinquin, from France, holds a Ph. D. in Applied Mathematics and is a Medical Doctor from Grenoble University. He is Professor of Public Health (Medical Informatics) and heads TIMC (*Translational Innovation in Medicine and Complexity, CNRS / Univ. Grenoble Alpes*), a research Unit devoted to Health Technology and Translational Research. He pioneered Computer-Assisted Medical Interventions (CAMI) and received the CNRS silver and innovation awards. He is co-author of 155 papers and 43 patents. He recently turned on intra-body energy scavenging in order to power implanted medical devices, which implied novel sterilization strategies.

He was commissioned by CNRS and CEA to set up a French interdisciplinary task force devoted to exploring the possibility of recycling surgical masks and FFP2. This task force now brings together 49 academic, hospital and industrial teams.

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Preliminary Results of a French “Re-Use surgical masks and FFP2 (N95)” Task Force

Philippe.Cinquin@univ-grenoble-alpes.fr

- **May 21, 2020**
- **CNRS – CEA – INSERM – INRS - ANSES – DGA – IRSN - French Hospitals and Universities**
- **IONISOS – AIR LIQUIDE – INGENICA – 2BINNOV – ALPHATEC - AURORA – MT2I - SEITZ – APTAR - NUVIA**
- [1]TIMC (UMR 5525 CNRS-UGA-G-INP-VetagroSup), [2]CIC-IT1406 (INSERM-CHUGA-UGA), [3]Service d’Hygiène, Pôle de Santé Publique, CHUGA, [4]Service de Stérilisation, Pôle Pharmacie CHUGA, [5]ARCNUCLEART, CEA-Grenoble, [6]IMT Atlantique, GEPEA UMR CNRS, [7]INRS Nancy, [8]IONISOS & STERYLENE, [9]CERMAV, [10]PUMA, [11]Service de bactériologie, CHUGA, [12] Equipe VirPAth, Centre International de Recherche en Infectiologie (CIRI), Inserm U1111, CNRS UMR5308, ENS Lyon, [13]Service de Virologie, CHUGA, [14]MT2I, [15]Direction de la Recherche en Santé et Innovation, CHUGA, [16]CHU de Nantes, [17]LEGI (CNRS- UGA), [18]LRGP (CNRS–Univ. de Lorraine), [19]Centre d’Etude des Pathologies Respiratoires (CEPR, Inserm U1100), Université de Tours, [20]Unité de Parasitologie et Mycologie – Médecine tropicale, CHRU et Université de Tours, [21] Plateforme IBiSA de Microscopie Electronique, CHRU et Université de Tours, [22] Service de Bactériologie-Virologie-Hygiène Hospitalière, CHRU et Université de Tours, [23] Service de Médecine interne et maladies infectieuses, CHRU et Université de Tours, [24] ANSES, [25] ICMCB, [26] IRCELYON, [27] Mines Saint-Etienne U1059, [28] Air Liquide, [29] INGENICA, [30] 2BINNOV, [31] AURORA, [32] DGA, [33]CIC-IT1433 (INSERM-CHU Nancy), [34]IRSN, [35]LPGP, [36]CERTAM, [37]ICSM, [38]Seitz, [39]APTAR, [40]Nuvia, [41]G2ELAB (UMR5269 CNRS-UGA), [42]STERIPURE, [43]UJM GIMAP EA 3064, [44]NIMBE, UMR 3685 CEA, CNRS, Université Paris-Saclay, CEA Saclay, [45] DES-Service d'Étude du Comportement des Radionucléides (SECR), CEA, Université Paris Saclay, [46]LITEN/DTNM, Plateforme Nanosécurité, CEA Grenoble, [47]Alphatec, [48]LGP2, [49]Paul Boyé

Philippe Cinquin[1,2], Jean Pierre Alcaraz[1], Caroline Landelle[1,3], Catherine Guimier-Pingault[4], Laurent Cortella[5], Christophe Albino[5], Karine Froment[5], Laurence Le Coq[6], Aurélie Joubert[6], Yves Andrès[6], Sandrine Chazelet[7], Sophie Rouif[8], Muriel Ferry[45], Sophie Le Caër[44], Stéphane Esnouf[45] , Laurent Heux[9], Jean-Paul Brion[10], Olivier Epaulard[10], Sophie Silvent[2], Isabelle Bourdry[2], Maud Barbado[2], Valentin Paran[1], Théophile Tiffet[1,2], Max Maurin[11], Olivier Terrier[12], Patrice Morand[13], Pascal Poignard[13], Raphaële Germi[13], Daniel Garin[14], Abdelaziz Bakri[1], Nawel Khalef[1], Joël Gaffé[1], Camille Ducki[15], Jean- Michel Nguyen[16], Yves Dubief[17], Dominique Thomas[18], Augustin Charvet[18], Nathalie Bardin-Monnier[18], Jean-Christophe Appert-Collin[18], Olivier Dufaud [18],, Jean-Luc Bosson[1,2], Elsa Bodier-Montagutelli[19], Guillaume Desoubeaux[19,20], Joeffrey Pardessus[19], Déborah Diakite[19], Laurine Allimonier[19], Virginie Vasseur[19], Laurent Vecellio[19], Philippe Roingeard[21], Philippe Lanotte[22], Louis Bernard[23], Mustapha Si-Tahar[19], Nathalie Heuzé-Vourc'h[19], Nicolas Eteradossi[24], Béatrice Grasland [24], Paul Brown [24], Evelyne Lemaître [24], Chantal Allée [24], Yannick Blanchard [24], Lionel Bigault [24], Hélène Quenault [24], Cyril Aymonier[25], Catherine Pinel[26], Jérémie Pourchez[27], Juan-Fernando Ramirez[28], Olivier Perraud[29], Bastien Brun[30], Jann Laarman[31], Yannick Morel[32], Marine Beaumont[33], Claire Dessale[33], Alexandre Moreau-Gaudry[1,2], François-Xavier Ouf[34], Jean-Michel Bonnet[34], Laurent Bouilloux[34], Laurent Ricciardi[34], Céline Monsanglant-Louvet[34], Soleiman Bourrous[34], Nicolas Jidenko[35], Jean-Pascal Borra[35], David Préterre[36], Frédéric Dionnet[36], Guillaume Balarac[17], Simon Clavaguera[46], Sébastien Artous[46], Thomas Zemb[37], Max Da Silva Matos[38], Ralf Doering[38], Alexander Seitz[38], Krystel Limouzin[39], Bruno Lancia[40], Alain Sylvestre[41], Olivier Bourgois[42],Paul Verhoeven[43], Yann Chevelu[47], Naceur Belgacem[48],François Lustenberger[49]

Synthesis of positive results obtained on FFP2

- **The following methods kill SARS-CoV-2 and respect FFP2 filtration**
  - NB virus reduction > 6 $\log_{10}$ in presence of stains (FBS 10% or saliva)
- **Dry Heat**
  - 5 cycles of [Use simulation (1 hour at 37°C and 85% Relative Humidity) + **30 min 95°C + 1 day**]
  - **2 hours at 70°C** (NB FFP2s resist 24h by EN149). NB 1 hour at 70°C was **not** sufficient!
- **Moist heat 1 hour 70°C + 75% RH**
- *IONISOS:* **Ethylene Oxide** (known to kill also resistant bacteria)
  - > 2 cycles
  - Residual < 0,002 mg/FFP2 (threshold ISO 10993-7 = 4 mg/24h or 60 mg/30 days)
- *INGENICA:* **UV-C:** 1 J/cm^2 for 5 layers FFP2, 0.5 J/cm^2 for 3 layers surgical masks (takes ~ 2 mn), up to 4 cycles
- *APTAR:* **ClO_2** envelopes 2 hours, up to 10 cycles
- *NB we did not test BATTELLE:* H_20_2 vapor (FDA approved, US)

Other results obtained on FFP2

- **FFP2 filtration is respected by**
  - 2BINNOV: Ozone exposition
  - Super critical CO_2 (with an adapted protocol, result on 1 FFP2)
  - Hyperbaric H2
  - Washing up to 60°C **without detergent**
- **No dangerous residuals of the interaction of all tested treatments with FFP2 components**
- **Dry Cleaning is very promising**
  - filtration ~ 80-90%, regenerated to > 94% by several methods, including corona effect application
- **Filtration loss (loss of electret effect)**
  - Washing **with detergent** (filtration ~ 60%)
  - Irradiation (gamma / beta, filtration ~ 80%)
  - *Autoclave* (121°C plateau of 20 minutes, filtration ~ 80% - 90%). *NB may depend on FFP2 brand, Belgian teams recommend this protocol*

Synthesis of results obtained on surgical masks

- **All the following completely sterilizing methods respect filtration and breathability**
  - **5 cycles** [washing + autoclave]
  - **3 cycles** [washing + ethylene oxide]
  - **3 cycles** [washing + 20 kGy irradiation – gamma or beta]
- **Supercritical CO_2, hyperbaric H_2**
  - We are exploring microbiological burden reduction of these methods
- **And all the other processes working for FFP2**

Risks of recycling single use masks

- **If washing with detergent cannot be applied**
  - Organic deposits may protect virus and bacteria
  - We apply “realistic scenarios” (virus inoculation with saliva) or worst case scenario (10% FBS, much more proteins than in biological secretions)
- **If virus is killed, but not mycobacteria**
  - “Individual” solutions work (UV-C, ClO_2, dry or moist heat)
  - For collective solutions, we recommend use of micro-porous nominative envelopes (to eliminate the risk of bacterial cross-contamination)

Next steps

- **Improve methods and accumulate experiments**
- **Launch “real conditions trials on volunteers” (ethical applications to be filed very soon)**
  - **Surgical masks:** 5 cycles [use + washing + treatment], with treatment =
    - Autoclave
    - Gamma Irradiation 20 kGy
    - Beta Irradiation 20 kGy
    - Ethylene Oxide
  - **FFP2:** 3 cycles “use + treatment », with treatment =
    - 30 minutes at 90°C dry heat + 1 day
    - 1 hour at 70°C and 75% Relative Humidity
    - Ethylene Oxide
    - UV-C (INGENICA)
    - ClO_2 (APTAR)

Panelist

Byungnam Kim, Principal Researcher-KAER

Mr. Byungnam Kim, from Korea holds the degrees of Ph.D. in Chemical Engineering(radiation chemistry) from the University of Yeungnam, Korea, M.Sc. and B.Sc are as before. And He had a postdoctoral course at the university of Maryland for two years.

He had more than 20 years of experience on the field of radiation chemistry and radiation processing in Korea, he has been working at Korea Atomic Energy Research Institute[KAERI] since 2009. He is currently the Head of the irradiation facilities at the Advanced Radiation Technology Institute[ARTI] of the KAERI.

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Mechanical properties and filtration performance of respiratory mask by ionizing irradiation [E-beam & Gamma]

J-.M.YUN, H.KIM, H.S.KIM, S.J.KIM, Y-.M.LIM, J.H.HA, B.KIM*
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Acknowledgments :

We would like to thank Ph. D. candidate J-O Jeong, and master course students Y-A Kim, and D-M Yun for their experimental support

KAERI
Korea Atomic Energy Research Institute

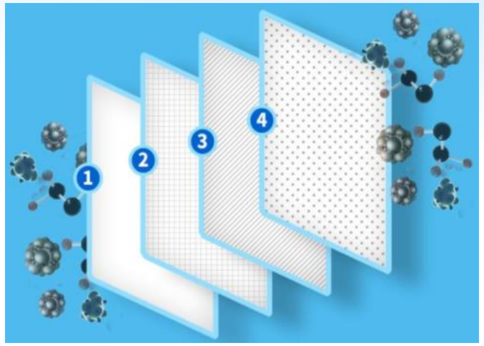
01 Structure of Commercial KF94 Mask

Model & Manufacture

- ➢ Made by may& Co., Korea
- ➢ Authorized by KFDA

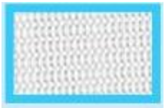
Commercial KF94 Mask

4-Layered Protection Filter



Inner Filter

Electrostatic Filter

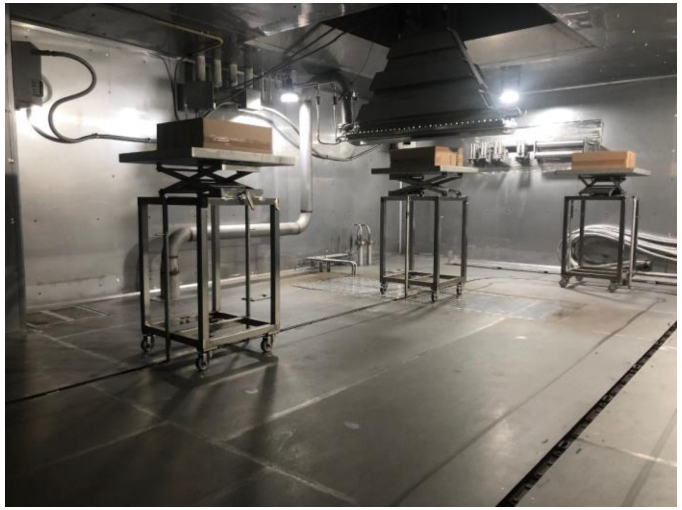


Middle Filter

Outer Filter

02 Radiation Technology

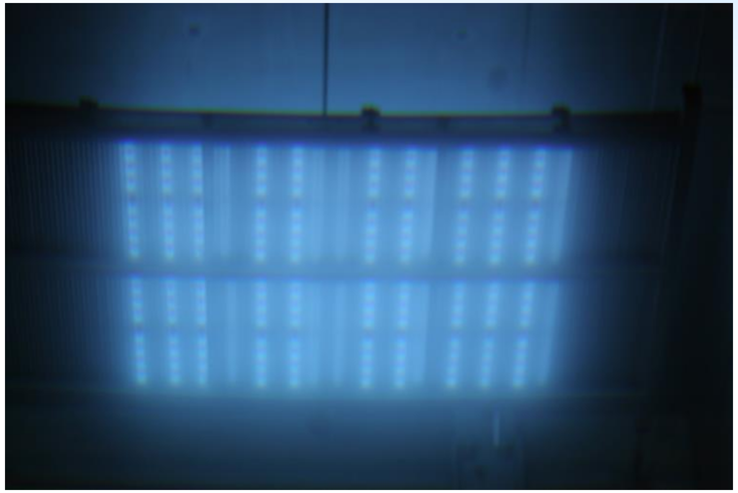
» Ebeam irradiation to mask



	Dose (kGy)	Energy (MeV)	Dose Rate (kGy/s)	Remarks
#1	9	2.5	18	- In air - In vacuum
#2	18	2.5	18	- In air - In vacuum
#3	24	2.5	18	- In air - In vacuum

- ➢ The Dose was controlled by current and conveyor speed

» Gamma irradiation to mask

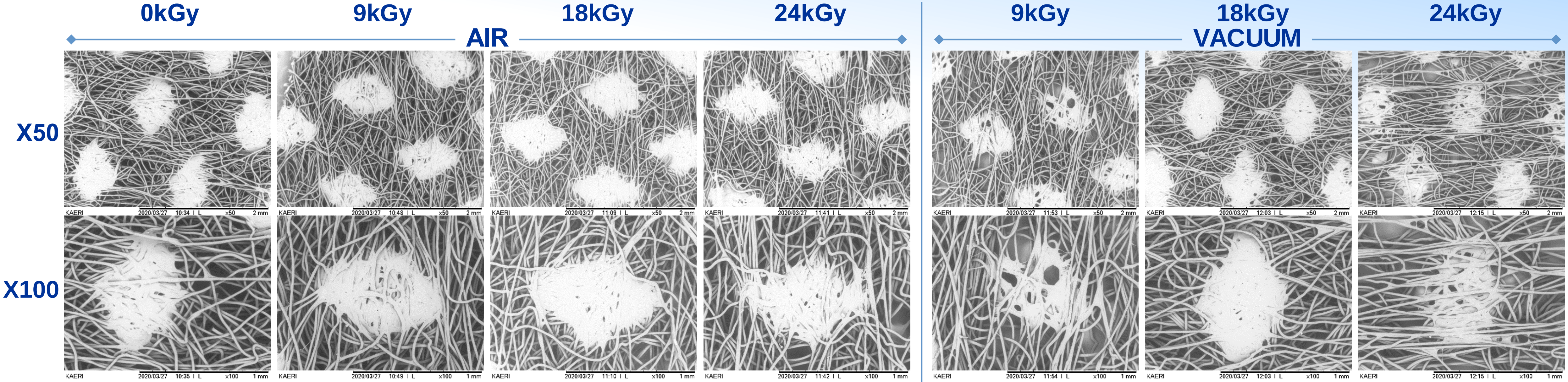


	Dose (kGy)	Dose Rate (kGy/h)	Remarks
#1	9	5	- In air - In vacuum
#2	18	5	- In air - In vacuum
#3	24	5	- In air - In vacuum

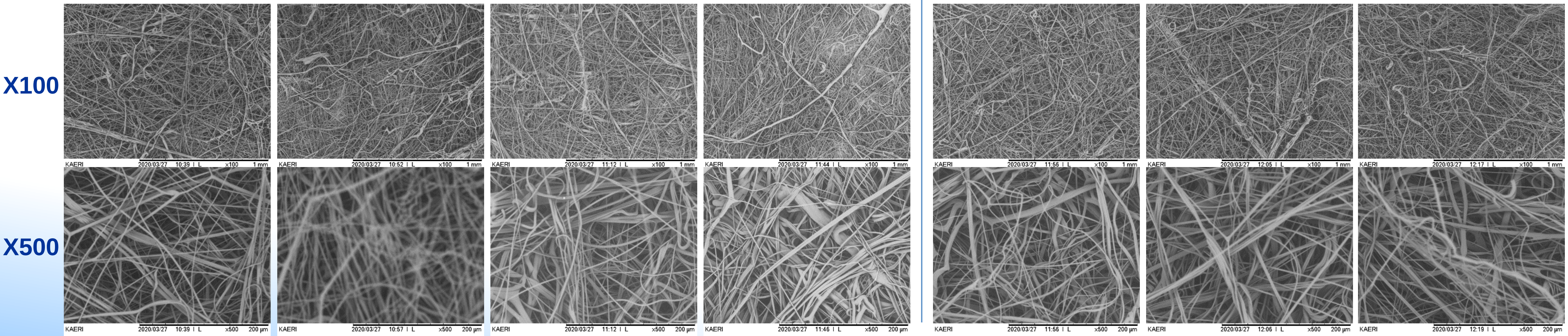
- ➢ The Dose was controlled by irradiation time and distance from source

03 SEM Morphology : EB

1. Inner Filter

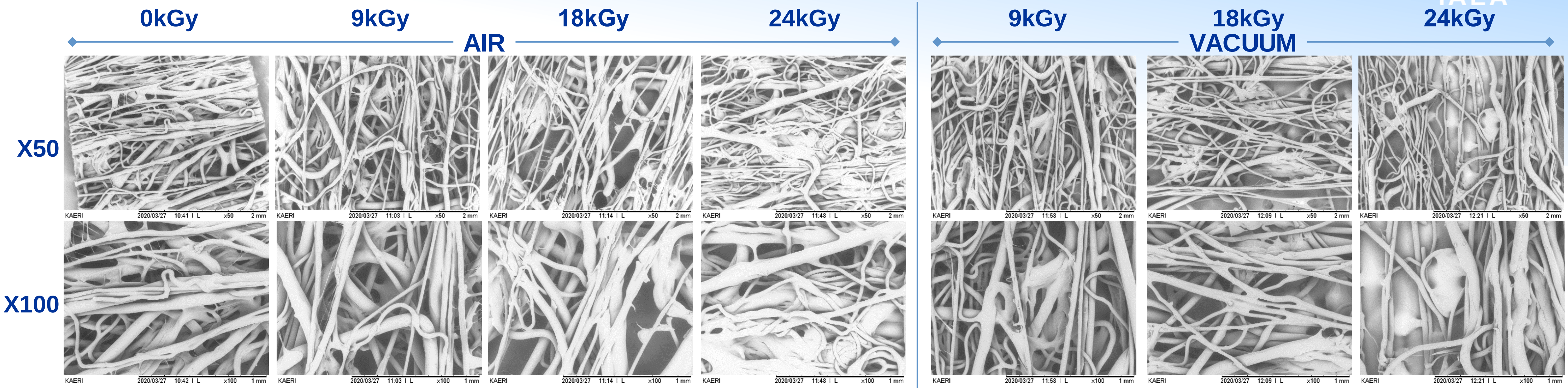


2. Electrostatic Filter

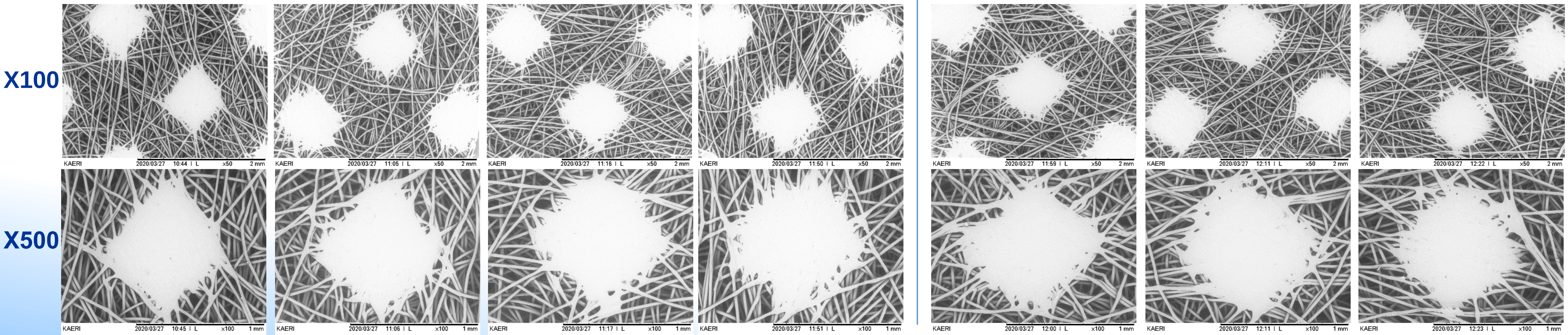


03 SEM Morphology : EB

3. Middle Filter



4. Outer Filter



03 SEM Morphology : Gamma

1. Inner Filter

0kGy 9kGy 18kGy 24kGy

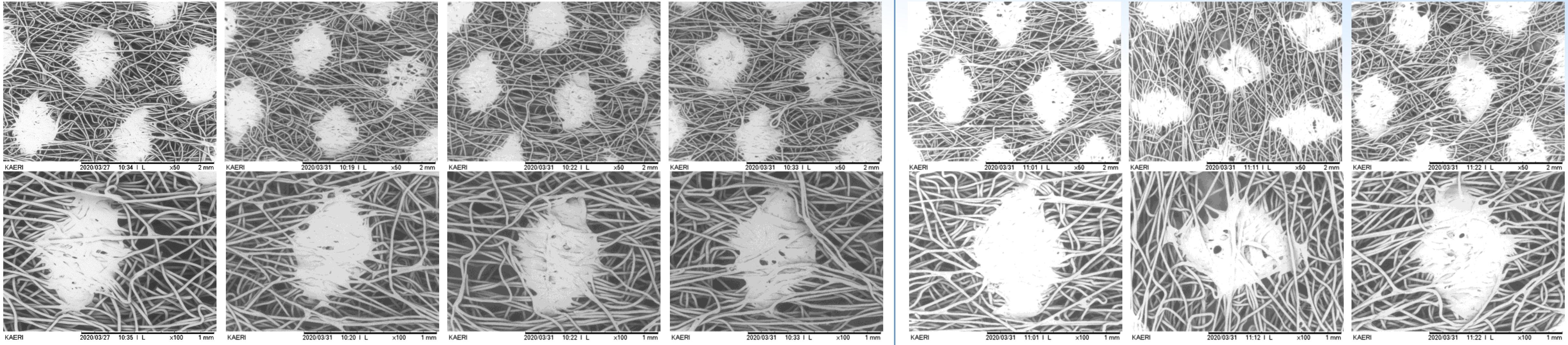
AIR

9kGy 18kGy 24kGy

VACUUM

X50

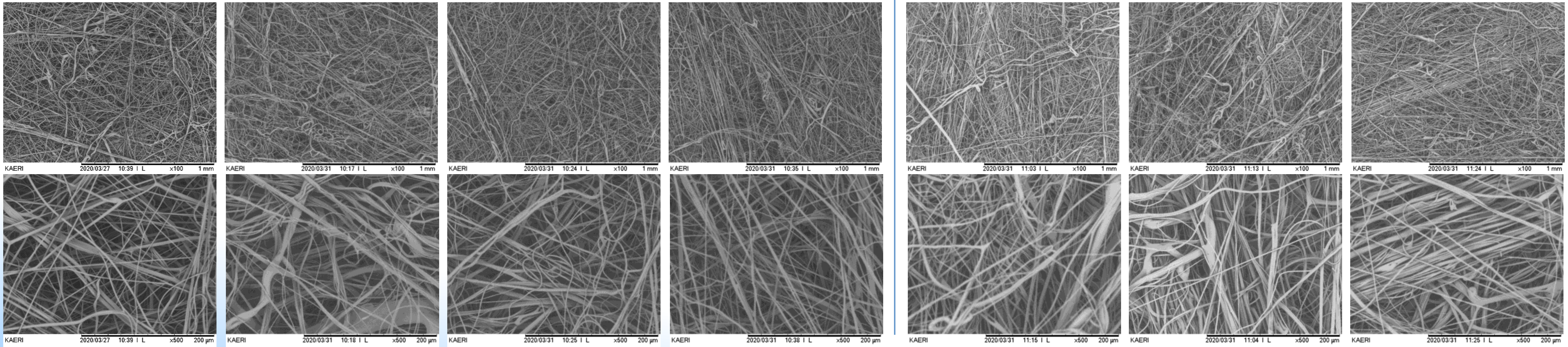
X100



2. Electrostatic Filter

X100

X500



03 SEM Morphology : Gamma

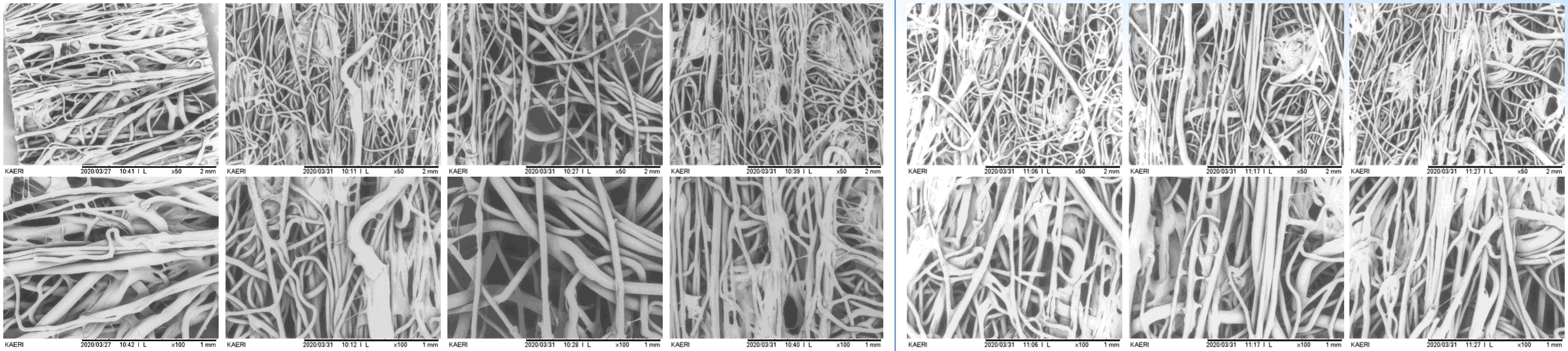
3. Middle Filter

AIR: 0kGy, 9kGy, 18kGy, 24kGy

VACUUM: 9kGy, 18kGy, 24kGy

X50

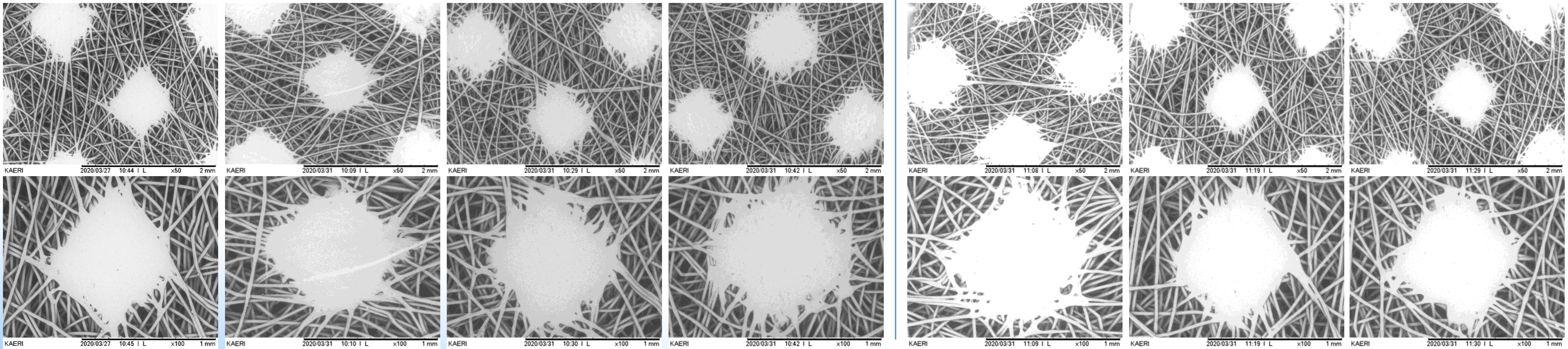
X100



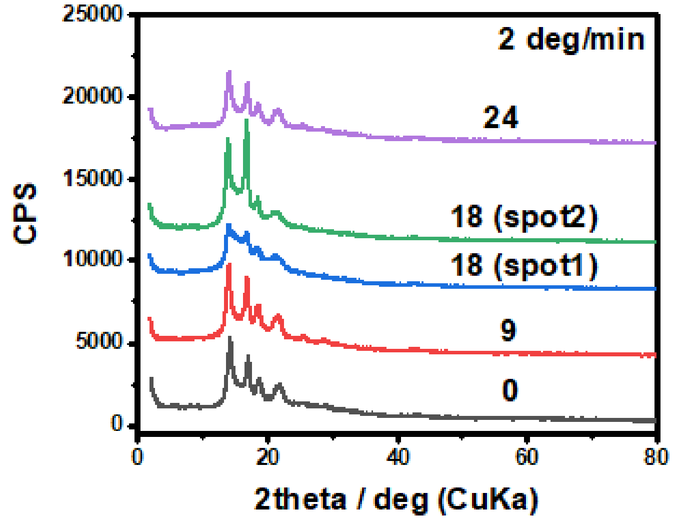
4. Outer Filter

X100

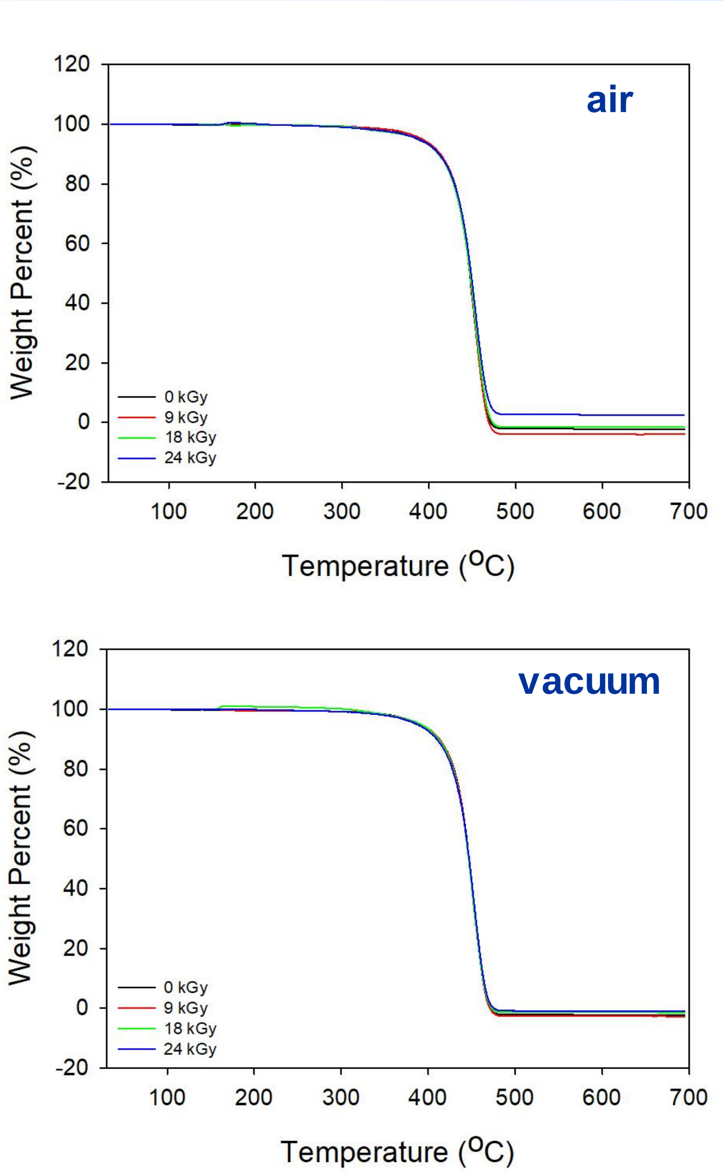
X500

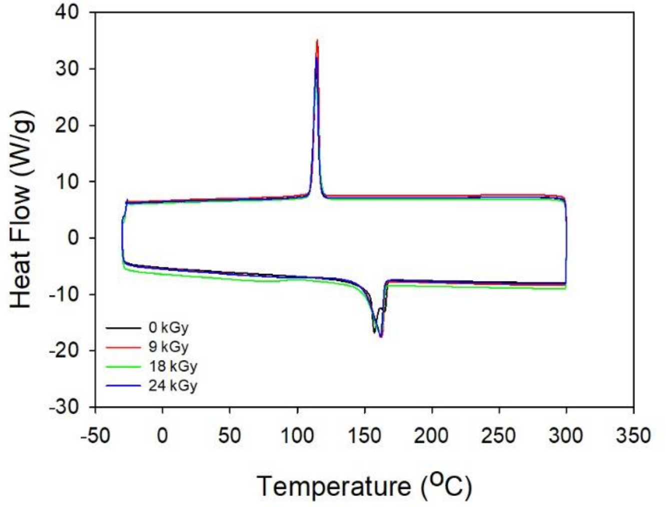


04 Crystallinity and Thermal Analysis[E-beam]



XRD result of electron beam irradiated electrostatic filter under air



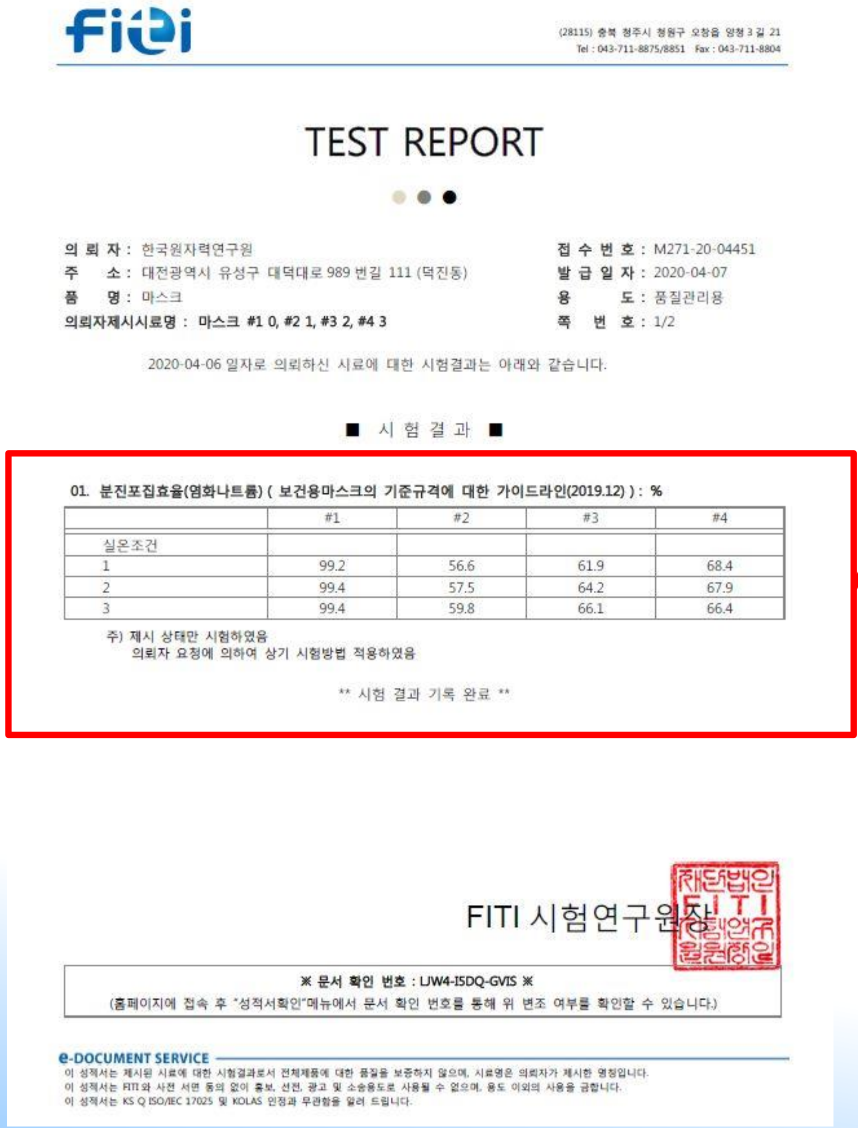


DSC result of electron beam irradiated electrostatic filter under air

TGA result of electron beam irradiated electrostatic filter under air and vacuum

04 Filtration Test

Filtration Test



Fiti

(28115) 충북 청주시 청원구 오창읍 양청 3 길 21
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TEST REPORT

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주 소 : 대전광역시 유성구 대덕대로 989 번길 111 (덕진동)
품 명 : 마스크
의뢰자제시시료명 : 마스크 #1 0, #2 1, #3 2, #4 3

접 수 번 호 : M271-20-04451
발 급 일 자 : 2020-04-07
용 도 : 품질관리용
쪽 번 호 : 1/2

2020-04-06 일자로 의뢰하신 시료에 대한 시험결과는 아래와 같습니다.

■ 시험결과 ■

01. 분진포집효율(염화나트륨) (보건용마스크의 기준규격에 대한 가이드라인(2019.12)) : %

	#1	#2	#3	#4
실온조건				
1	99.2	56.6	61.9	68.4
2	99.4	57.5	64.2	67.9
3	99.4	59.8	66.1	66.4

주) 제시 상태만 시험하였음
의뢰자 요청에 의하여 상기 시험방법 적용하였음

** 시험 결과 기록 완료 **

FITI 시험연구원장

※ 문서 확인 번호 : LJW4-ISDQ-GVIS ※
(홈페이지에 접속 후 "성적서확인"메뉴에서 문서 확인 번호를 통해 위 변조 여부를 확인할 수 있습니다.)

e-DOCUMENT SERVICE

이 성적서는 제시된 시료에 대한 시험결과로서 전체제품에 대한 품질을 보증하지 않으며, 시료명은 의뢰자가 제시한 명칭입니다.
이 성적서는 FITI와 사전 서면 동의 없이 홍보, 선전, 광고 및 소송용도로 사용될 수 없으며, 용도 이외의 사용을 금합니다.
이 성적서는 KS Q ISO/IEC 17025 및 KOLAS 인정과 무관함을 알려 드립니다.

Irradiation sample

- ➢ Beam energy : 2.5 MeV in air

Room Temperature				
	0 kGy	9 kGy	18 kGy	24 kGy
1	99.2%	56.6%	61.9%	68.4%
2	99.4%	57.5%	64.2%	67.9%
3	99.4%	59.8%	66.1%	66.4%
Avg.	99.3%	57.9%	64.1%	67.6%

Method

- ➢ The filtration test can be performed by approved guideline of KFDA
- ➢ Equipment and experiment conditions are almost identical to EN149.

IAEA
International Atomic Energy Agency

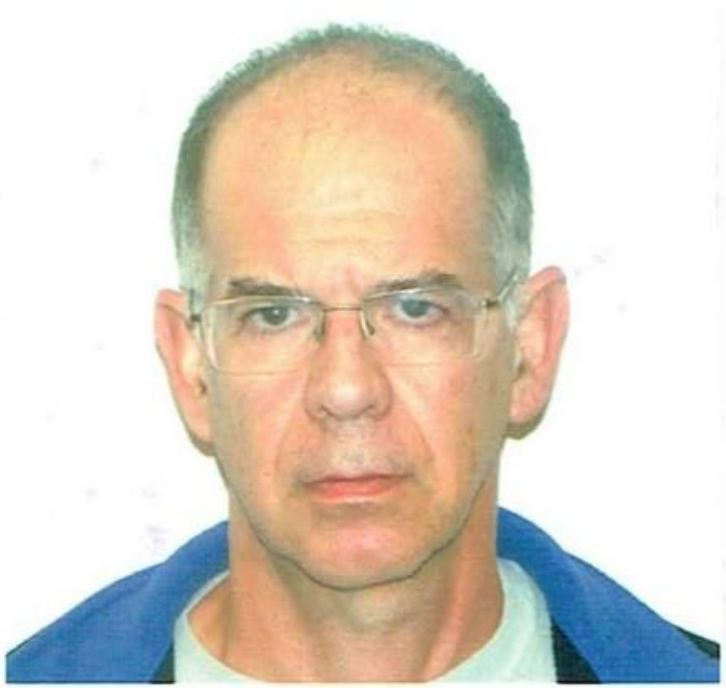
05 Conclusion

- Mechanical Properties such as morphology SEM, TGA and DSC of KF94 masks are not significant change and doses from 9 to 24 kGy of electron beam and gamma radiation.

- However, filtering efficiency of irradiated masks were declined do severely suggests against using ionizing radiations a mask sterilization.

- This is mean that electrostatic effect of the mask was reduced by electron beam irradiation, It can be considered that sterilization is sufficiently possible by irradiation such electron beam, but it is difficult to limit the recycling due to reduced filter performance.

Panelist



Elazar Sarid- SNRC, Isarel

Professor Elazar (Eli) Sarid, from Israel, holds the degrees of Ph.D. in Physics from the Weizmann Institute, and B.Sc. In Physics from Tel Aviv University, Israel.

Trained as a plasma physicist, Professor Sarid has done his post doc at University of California, San Diego, worked at NRCN, Israel, and spent sabbatical leaves at UC Berkeley and CERN. He is a member of the antihydrogen ALPHA collaboration at CERN since 2005.

Since 2013 Prof. Sarid is the Chief Scientist of Soreq NRC, Israel. He is an adjunct professor at Ben Gurion University.

IAEA
International Atomic Energy Agency

THE FEASIBILITY OF STERILIZATION FOR REUSE OF DISPOSABLE MEDICAL EQUIPMENT: GAMMA IRRADIATION OF MEDICAL MASKS AND MEDICAL PROTECTIVE CLOTHING

I. GOUZMAN, H. DATZ, R. VERKER, A. BOLKER, L. EPSTEIN, L. BUCHBINDER, Y. FRIED and E. SARID
Soreq Nuclear Research Center (SNRC), Yavne, Israel

E. ZUCKERMAN
Sor-Van Radiation Ltd., Yavne, Israel

G. BOAZ
Israeli Ministry of Defense

Which respiratory masks have been tested?

3M 8710E Unvalved Cup-Shaped (FFP1)	
M3 KIMBERLY CLARK 62465	
3M aura 9332+ (FFP3)	
Cotton Respiratory Venus V-430 SLV (FFP3 NR)	

HP3 1102 (FFP2 NR D)	
3M 9501+ KN95 Mask Particulate Respirator	
Makrite Niosh N95 Cone Mask 9500	
BI WEI KANG KN95 - 9600 Folding Dust Respirator	

Radiation technology used and applied doses

- ☐ All irradiations were performed at Sor-Van irradiation facility, which operates a **Nordion's JS-6500 cobalt irradiator**.
- ☐ Sor-Van is a private company located at Soreq NRC (SNRC) area.
- ☐ Sor-Van provides sterilization services to the medical field, research institutions, hospitals and the food manufacturing plants.
- ☐ **Applied doses** for masks irradiations : **6 kGy - 60 kGy**

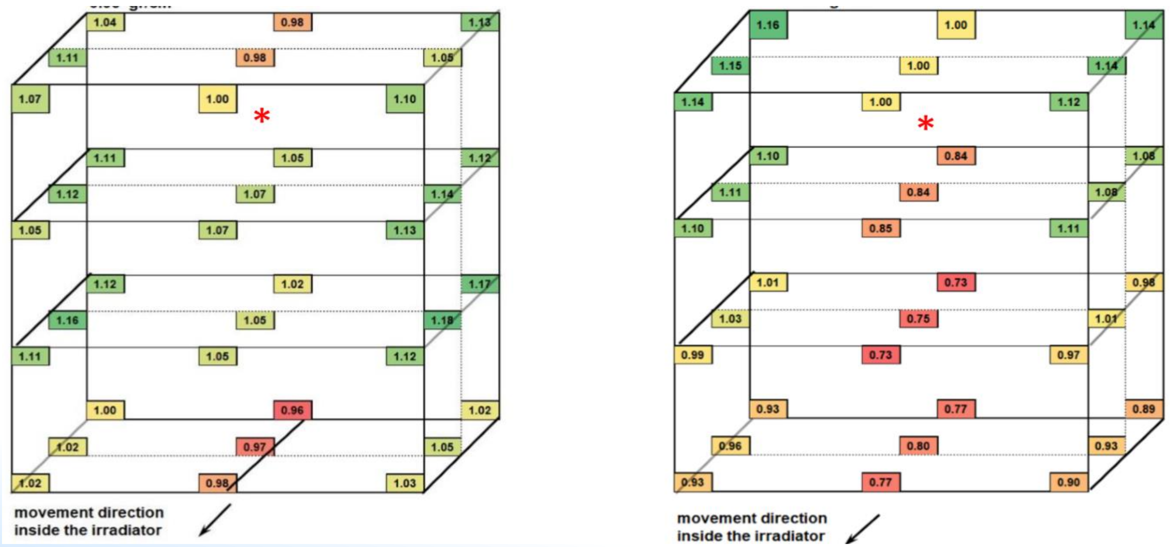
(60 kGy @ ~5 hr. of irradiation)

Sor-Van irradiation facility DUR (Dose Uniformity Ratio) measurements

Density gr/cm^3	Target Dose kGy	Normalized Minimum Dose	Normalized Maximum Dose	DUR Max./Min. Dose
0.05	31.8	0.96	1.18	1.23
0.32	17.8	0.73	1.16	1.60

Normalized dose in the container volume

Each point represents the average dose of 3 measurements.

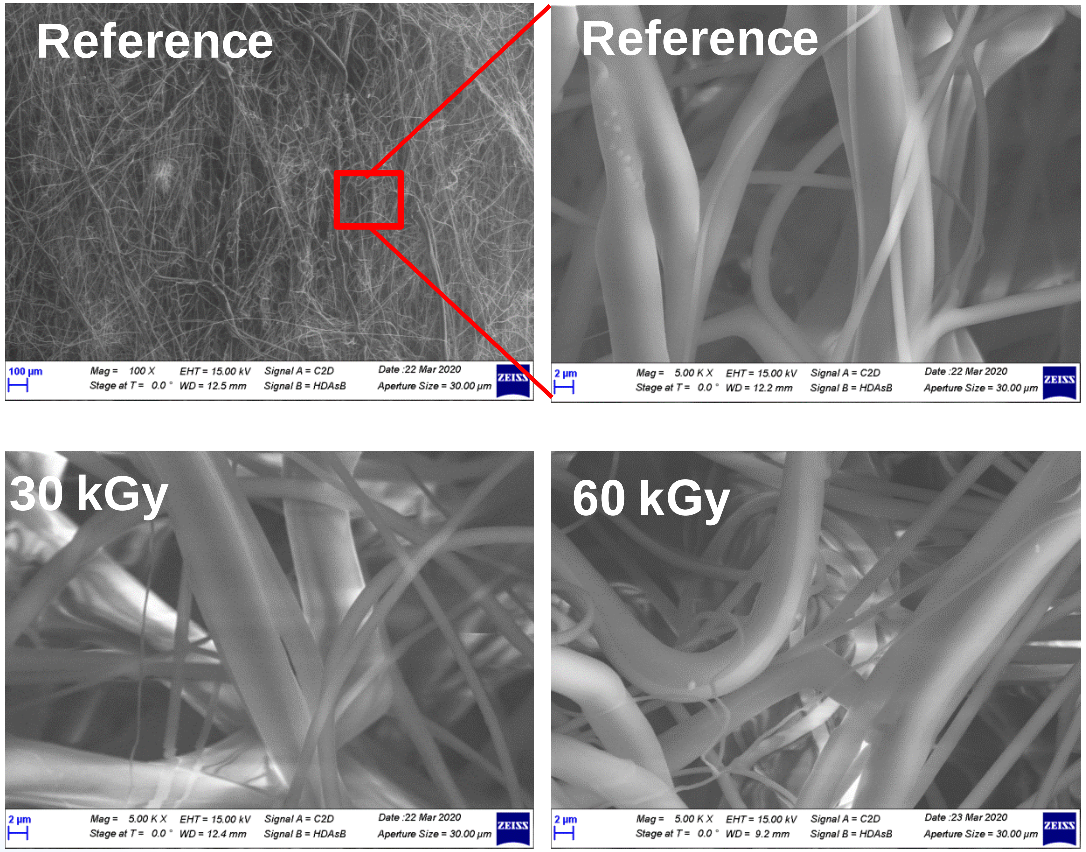


0.05 gr/cm^3

0.32 gr/cm^3

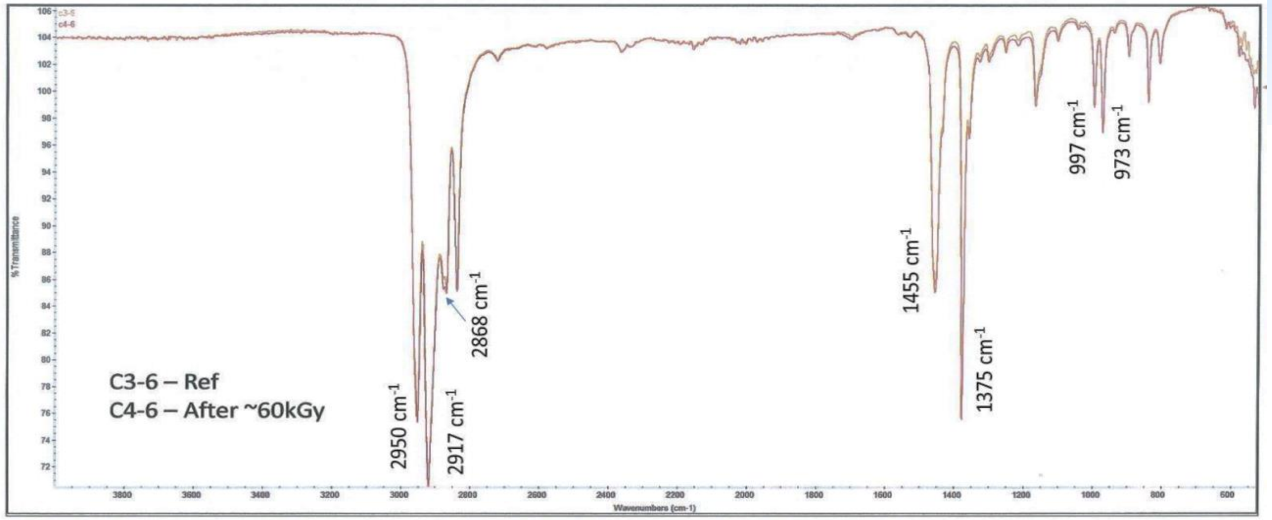
How does irradiation affect the microstructure?

3M aura 9332+ (FFP3) mask – internal PP layer



SEM measurements: No morphological changes

FTIR measurements: No changes in the chemical structure



Changes in mechanical properties: outer layer of HP3 1102 (FFP2 NR D)

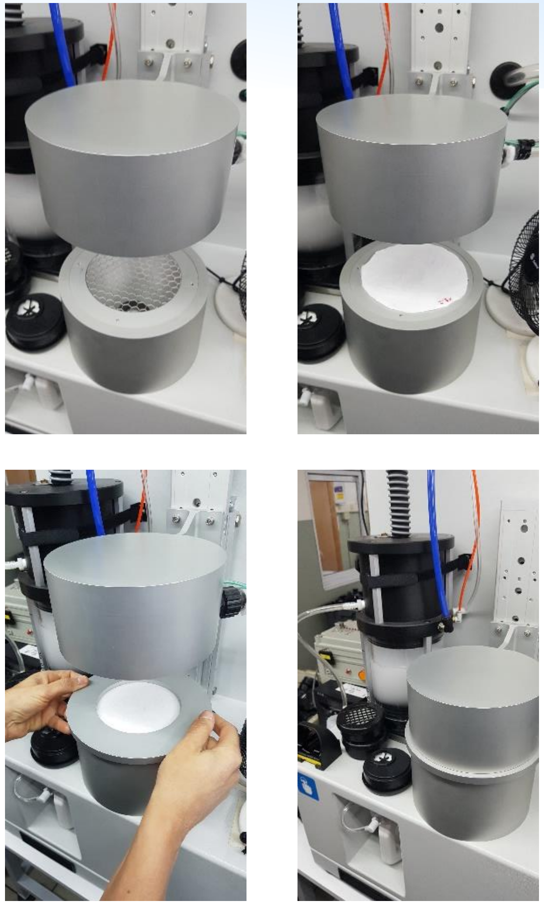
Sample	Ultimate tensile stress (MPa)	Ultimate tensile strain (%)
Reference	11.7 ± 0.9	101.8 ± 12.4
50 kGy	7.6 ± 0.5	29.8 ± 2.3

Filtration performance tests

KN95

N95

Sample name	Dose [kGy]	Filtration Efficiency (%)	Remarks
Z1	0	95.3	Flat Sheet N95 Filter Media
X1	30	34.3	Flat Sheet N95 Filter Media
Y1	60	36.4	Flat Sheet N95 Filter Media
F3	6	56.3	3M 9501+ KN95
F5	32	64.0	3M 9501+ KN95
G1	0	99.9	Makrite Niosh N95
G6	32	64.8	Makrite Niosh N95
G4	32	65.1	Makrite Niosh N95 **vacuum sealed**
G8	60	64.6	Makrite Niosh N95 **vacuum sealed**



Surgical Mask: For non-irradiated mask the filtration efficiency is ~80%, after irradiation: ~30%

Much more promising- PPE tests

	Sample	Ultimate tensile stress (MPa)	Ultimate tensile strain (%)
	R1 - Reference	17.0 ± 2.1	22.8 ± 2.7
	R2 - 30 kGy	14.2 ± 2.3	18.7 ± 2.6
	R2 - 60kGy	11.0 ± 1.3	16.3 ± 1.9
	T1 - Reference	3.0 ± 0.5	51.3 ± 16.2
	T2 - 30 kGy	2.5 ± 0.5	19.4 ± 3.9
	S1 - Reference	6.4 ± 0.3	68.6±8.2
	S2 - 30 kGy	8.7 ± 0.8	36.4 ± 2.4

No changes in: coloration, touch and pull, chemical structure and water-repellant properties were observed for the tested samples

Conclusions

- For all tested **medical masks**, no visual and morphological changes of the masks' materials were observed.
- FTIR indicated no changes in the chemical structure.
- Mechanical properties, both ultimate tensile stress and strain were diminished.
- Another observed effect of irradiation was appearance of a smell, which might be a result of radiation-induced oxidation of the filter material and/or additives.
- For the tested N95 and surgical masks we found that **the irradiation has significantly impaired the filtration efficiency for all irradiation doses**, from the low dose of 6 kGy, up to high dose of 60 kGy. This finding raises the question of the benefit and the feasibility of gamma irradiation sterilization of medical masks.

Panelist

Laurent Cortella - ARC-Nucléart / CEA

Mr Laurent Cortella, from France, graduated from the National Polytechnic Institute of Grenoble, where he received a Masters in nuclear engineering (French engineer diploma) and a PhD in materials science.

After 5 years experience in the field of radiation protection in CEA Grenoble, France, he joined ARC-Nucléart in 2002 where he assumes the head of facilities management, including the ^{60}Co irradiator. He supervises the irradiation services in different fields, firstly for cultural heritage preservation (I.e. biocidal treatments and consolidation with radio-curable resin) but he also participates in academic and applied research on natural or synthetic polymer for instance, or in qualification of material for nuclear or other industries.

French Task Force: RUM (Re-Use Mask)

A spontaneous consortium for exploring the feasibility of reprocessing medical masks

Involved in Ionizing Radiation Experiments:

L. Cortella, C. Albino, K. Froment, P. Cinquin, J.P. Alcaraz, L. Heux, C. Lancelon-Pin, M. Ferry, S. Esnouf, S. Rouif, F.X. Ouf, S. Bourrous, V.M. Mocho, L. Le Coq,
A. Joubert, Y. Andres

Which Respiratory Masks Have Been Tested?

- FFP2 Respiratory masks

Meltblown (M) / Spunbond (S) PolyPropylene

EN 149 European standard PPE

Duck bill flat fold masks w/o valve

Electret filter: electrically charged internal meltblown

- CA Diffusion ref. RP2_M

(SMMSS) (also EN 14683 medical device)

- Valmy, ref. VR202-03C

(SMMS)

- Surgical masks

Meltblown (M) / Spunbond (S) PolyPropylene

EN 14683 European standard MD

3-ply type II

- Kolmi OP air type II

(SMS)

- CA Diffusion ref. 1960

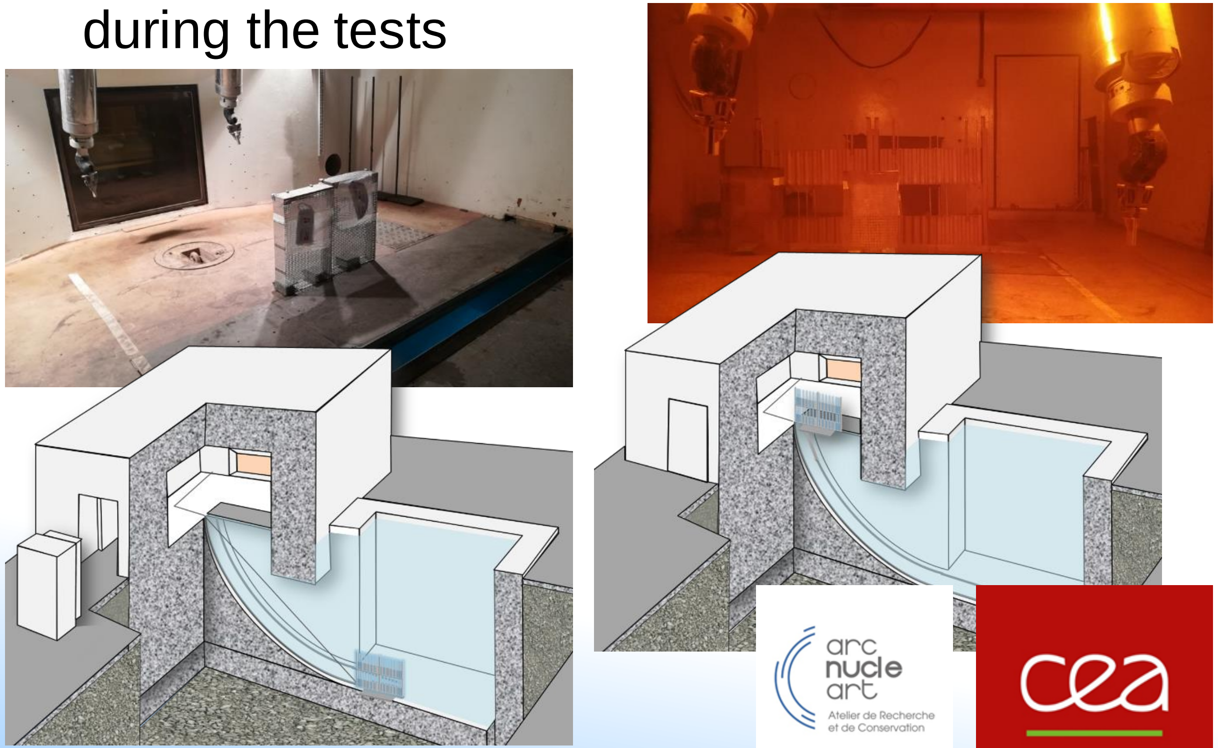
(SMSS) II-R type (anti splash)

Designed as single-use
Not designed to be sterilized

Irradiation

In ARC-Nucléart research gamma irradiator (Grenoble)

- ^{60}Co Pool Irradiator (1200 TBq on May 2020)
- Dose ranging from 1 kGy to 100 kGy
- Dose rate ranging from 0.5 to 2 kGy/h during the tests

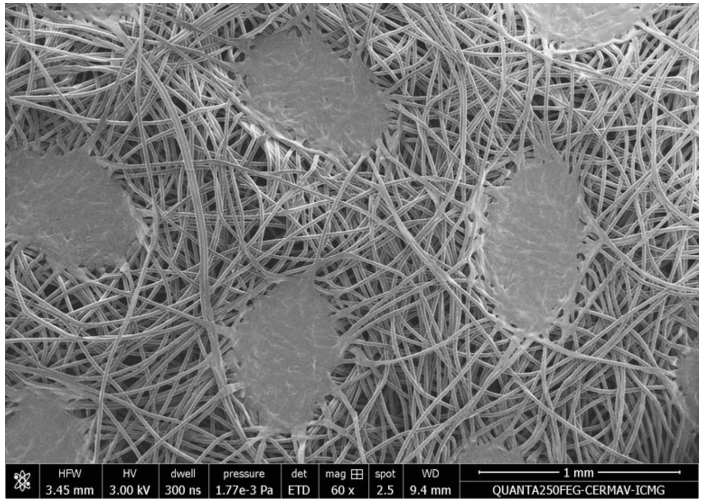


In Ionisos industrial e-beam facility (Chaumesnil)

- 10 MeV e^- accelerator (Mevex A29), 28 kW
- Routine conditions (2 faces)
- Several hundred kGy per minute
- Dose from 10 kGy to 120 kGy

Does Irradiation Affect SMS PP Materials Used In Masks?

No morphological changes



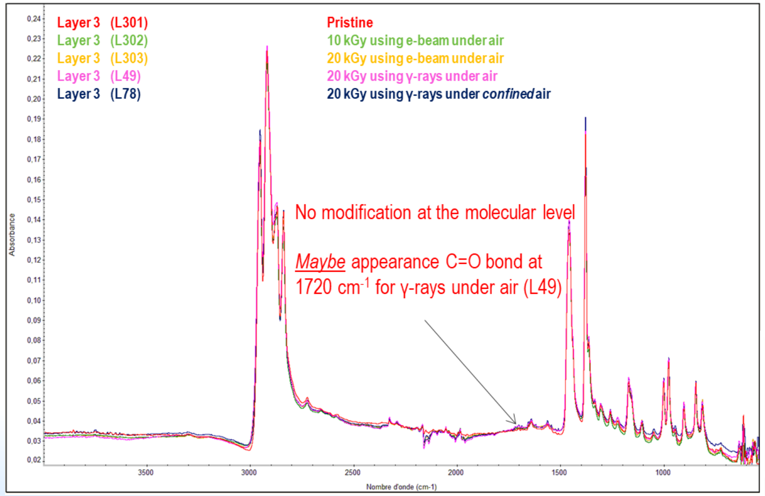
Irradiated internal meltblown

Few chemical evolution

- No modification of the PP at molecular level
- Few carbonyl bond when gamma irradiated in air

- Loss of antioxidant
- Low quantities of hindered phenol stabilizer degradation products evidenced

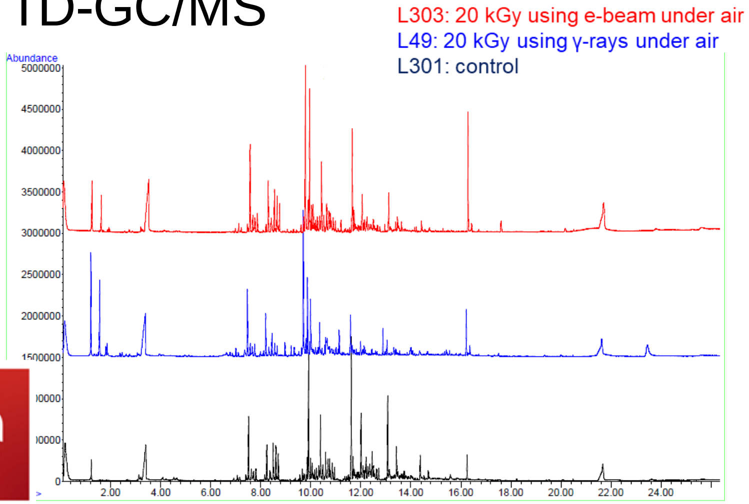
FTIR-ATR



No modification at the molecular level

Maybe appearance C=O bond at 1720 cm^{-1} for γ-rays under air (L49)

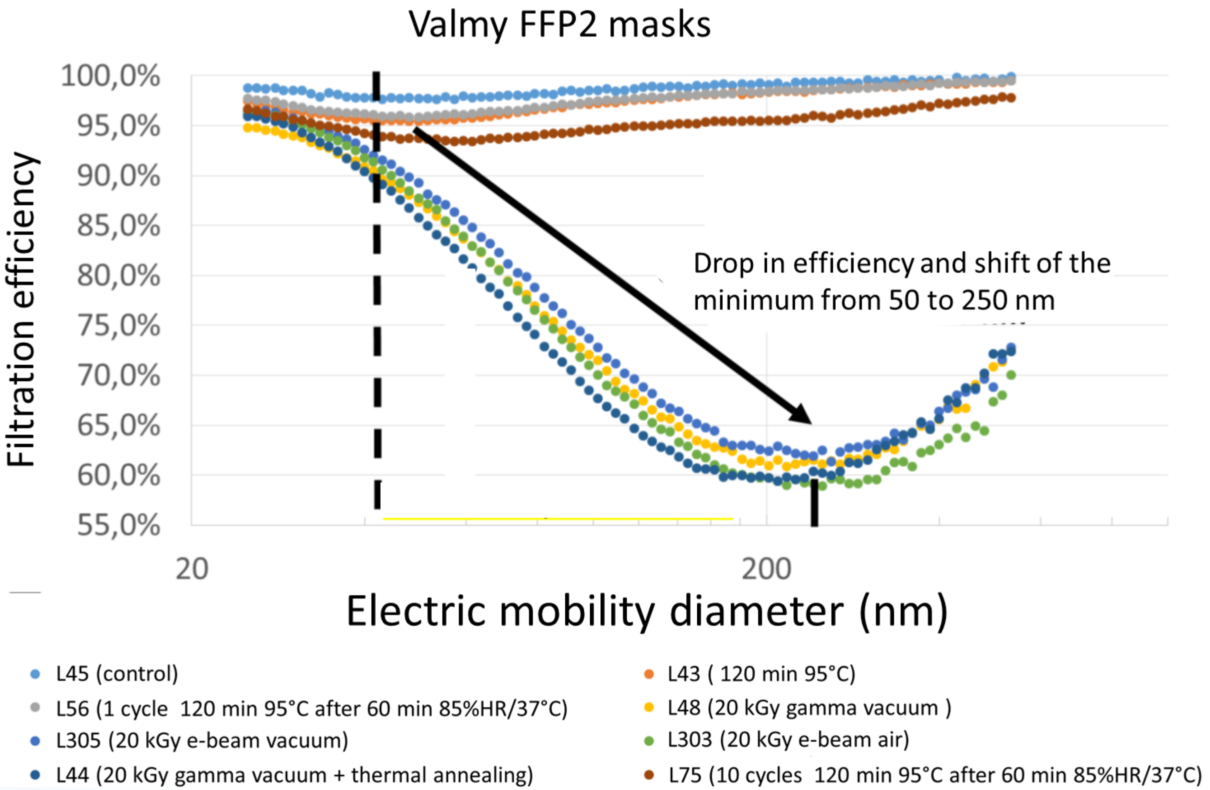
TD-GC/MS



Does Irradiation Affect The Filtration Performance?

IAEA

Submicronic filtration (FFP2)

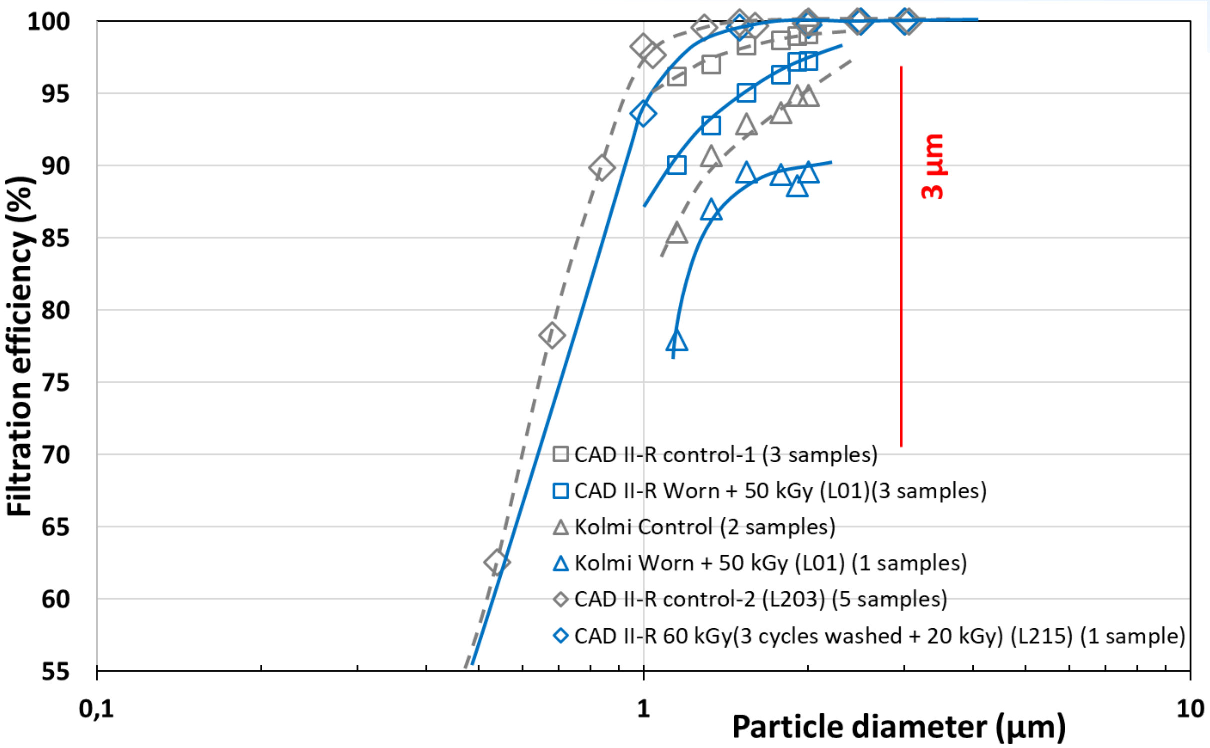


Drop in efficiency and shift of the minimum from 50 to 250 nm

IRSN
INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE

NaCl and paraffin submicronic filtration efficiency (APAVE EN 149) on 10 kGy e-beam irradiated FFP2 masks fall respectively to 82.3% and 58.2%

Micronic filtration (surgical)



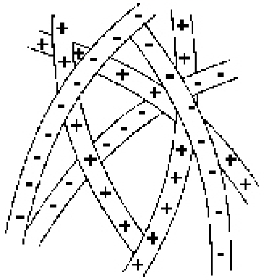
IMT Atlantique
Bretagne-Pays de la Loire
École Mines-Télécom

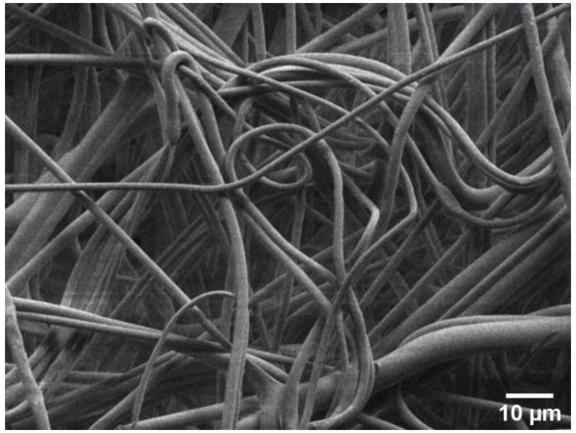
3 µm bacterian filtration (Centexbel EN 14683) on worn gamma or e-beam irradiated surgical masks : 86 to 88%

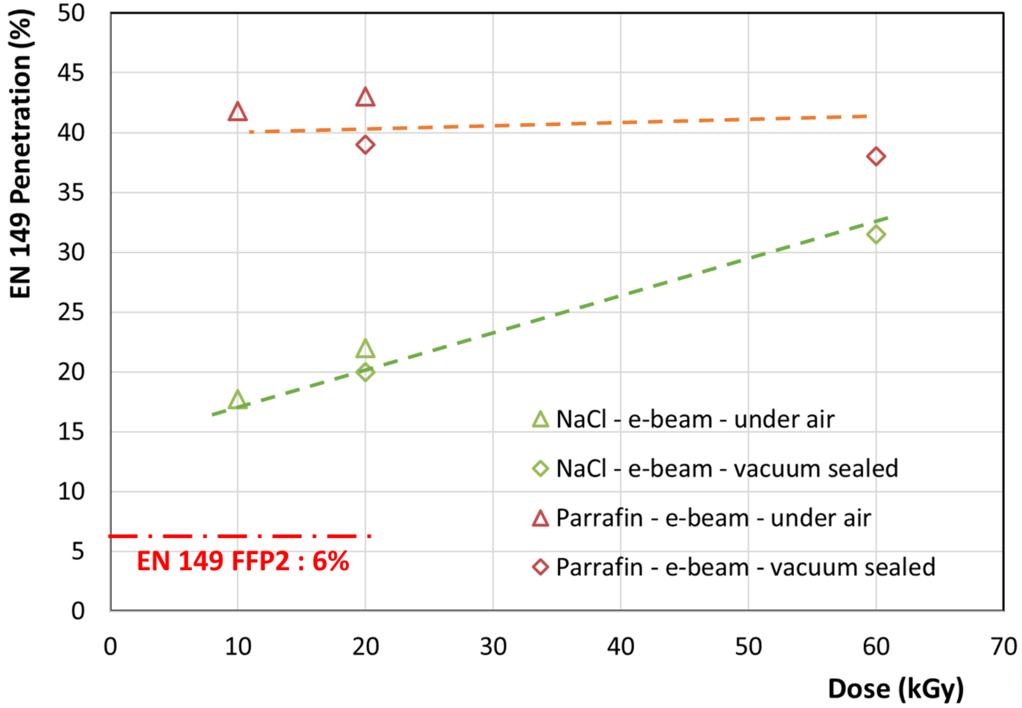
Ionizing Radiation And The So-Called "Electret" Filter

Electret: dielectric material in quasi-permanent state of electrical polarization (by analogy to magnet)

- Charged during the extrusion process by corona effect
- Allows a finer filtration by electrostatic effect without increasing the pressure drop (breathing resistance)







High density of ionization make the electret to discharge

- Even with doses of some kGy (see also Brazil results)
- Possibility of recharging the electret?

Conclusion

- Meltblown and Spunbond PP show good behavior until some tens of kGy irradiation (e-beam and gamma under vacuum)
- It seems possible to treat chirurgical masks under such conditions, possibly after washing.
  - 2nd reprocessing is not advised so far (may trigger PP post-oxidation phenomena after the second wearing or the second wash)
- Ionizing radiation strongly affect the electret of FFP2, N95 and equivalent
  - Possibility of recharging is understudy (?)

Panelist

Piotr Ulański - Poland

Mr Piotr Ulański, from Poland, holds Ph.D. in chemistry from the Lodz University of Technology, Poland. Besides his research activities at his home University in the team of professor Janusz Rosiak, he has spent many years at the Max-Planck-Institute for Radiation Chemistry, working with professor Clemens von Sonntag.

He has over 30 years of experience in radiation chemistry and technology of polymers, being a co-author of over 100 papers, book chapters and patents in this field. He is currently a professor of chemistry at the Lodz University of Technology, Poland, the Deputy Director of the Institute of Applied Radiation Chemistry, and a co-Editor-in-Chief of *Radiation Physics and Chemistry* (Elsevier).

EFFECTS OF ELECTRON-BEAM IRRADIATION ON THE STRUCTURE AND SELECTED PROPERTIES OF MELT-BLOWN POLYPROPYLENE UNWOVEN FABRIC USED IN THE PROTECTIVE FACE MASKS

P. FLAKIEWICZ, K. HODYR,
S. KADŁUBOWSKI, I. KRUCIŃSKA,
W. MACHNOWSKI, A.K. OLEJNIK,
B. ROKITA, G. SZPARAGA, P. ULAŃSKI

INSTITUTE OF APPLIED RADIATION CHEMISTRY,
FACULTY OF CHEMISTRY
&
FACULTY OF MATERIAL TECHNOLOGIES AND TEXTILE DESIGN

LODZ UNIVERSITY OF TECHNOLOGY, POLAND

Simple, surgical-type mask

Melt-blown PP

Photos: Wikipedia

FFP2/N95 class mask

Aim; irradiation conditions

To find out if melt-blown polypropylene (PP) nonwoven fabric, used as the filtration layer in simple, surgical-type face masks, can withstand electron beam (EB) irradiation with the typical sterilization dose of 25 kGy with no detrimental changes to its structure and basic properties.

Electron beam from a linear accelerator,
6 MeV, 12.5 kGy per pass
Doses: 12.5, 25, 50 kGy (masks)
25 kGy (custom-made PP fabric)

Samples irradiated:
- in air (open PE pouches)
- in vacuum (vacuum-sealed PE envelopes)
- in vacuum, with subsequent quarantine

What was tested ?

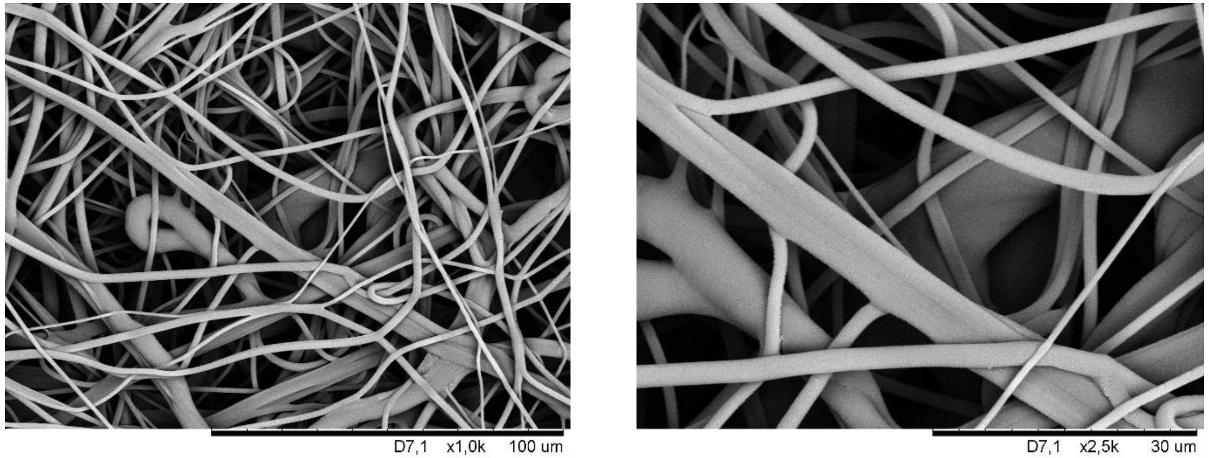
Structure of melt-blown PP fabric and fibers
SEM (Hitachi TM-1000), magnification up to 2,500 ×

Respiration resistance test and paraffin oil mist penetration test (EN 149:2001 + A1:2009).

Chemical structure & other properties
FT-IR (Thermo Nicolet Avatar 330), transm. mode
Organolepic study, observation
Post-effect (10 days)

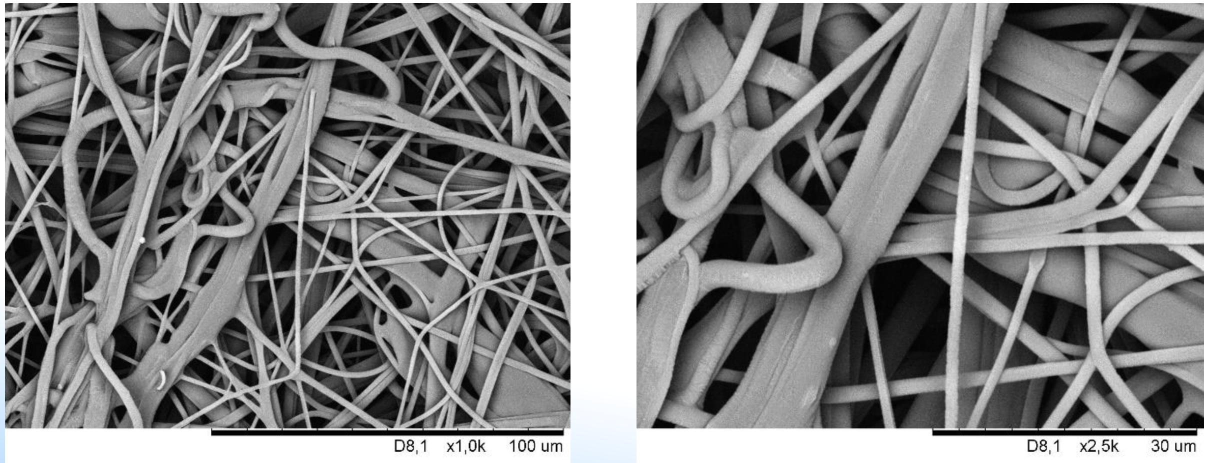
Main results (masks)

Middle layer, before irradiation



samples	11
positions	33
pictures	198

Middle layer, 50 kGy in air



No significant structural damage found

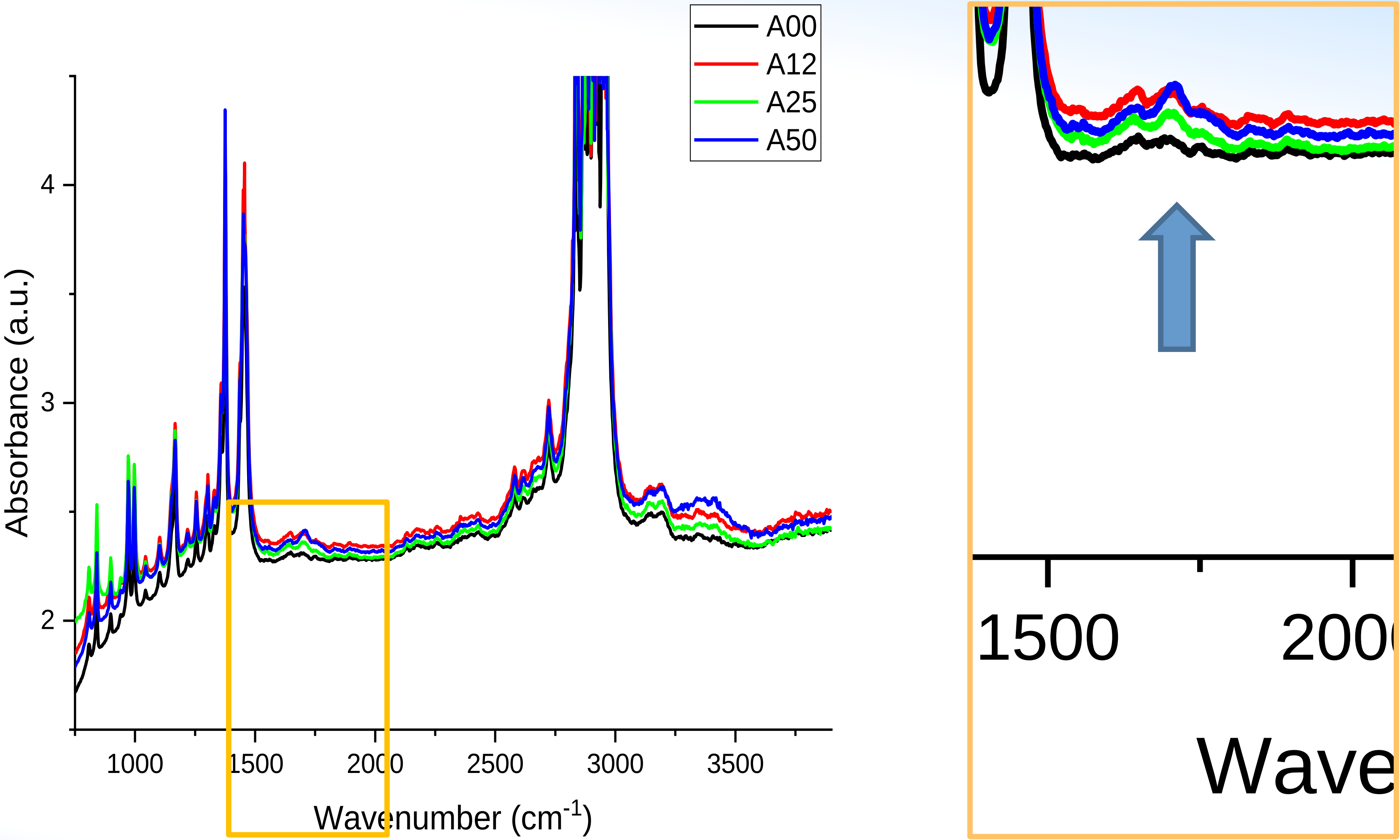
Main results (masks)

Table 2. Respiration resistance test and paraffin oil mist penetration test for unirradiated and irradiated masks, marked A00 and Q25, respectively (irradiation in vacuum at 25 kGy, sample kept for 3 days in unopened package, then analyzed).

Sample	**Inspiration resistance [mbar] (flow rate 30 l/min)**	**Inspiration resistance [mbar] (flow rate 95 l/min)**	**Exhalation resistance [mbar] (flow rate 160 l/min)**	**Paraffin oil mist penetration [%] (flow rate 95 l/min)**
A00	0.203	0.617	1.016	48.3
Q25	0.231	0.687	1.109	46.9
Requirem. according to EN 149:2001 + A1:2009	FFP1 ≤ 0.6 mbar FFP2 ≤ 0.7 mbar FFP3 ≤ 1 mbar	FFP1 ≤ 2.1 mbar FFP2 ≤ 2.4 mbar FFP3 ≤ 3 mbar	FFP1 ≤ 3 mbar FFP2 ≤ 3 mbar FFP3 ≤ 3 mbar	FFP1 ≤ 20% FFP2 ≤ 6% FFP3≤ 1%

No pronounced influence on respiration resistance and oil mist penetration

Main results (masks)



Very mild oxidation
(only when
irradiated in
the presence of air)

FIG. 2.1. Transmission-mode FT-IR spectra of the inner layer of the mask (25 g/m^2 melt-blown PP) non-irradiated and EB-irradiated in air. Numbers in the legend denote the dose in kGy.

Conclusions

- EB irradiation of simple masks or melt-blown PP fabric with typical sterilization dose does not lead to significant changes in structure, chemistry, respiration resistance and aerosol penetration of the tested masks and fabric.
- In our opinion, single EB irradiation with a typical sterilization dose of 25 kGy does not significantly impair the properties and usability of the simple, surgical-type masks, at least withing a short period (up to 10 days) after the irradiation.
- This conclusion should be taken with caution, since many factors can influence the outcome of irradiation. For particular masks at particular conditions, tests should be performed to verify the suitability of this technique in a given specific case.

Panelist

Avilash Cramer - MIT

Mr. Avilash Cramer, from Cambridge, Massachusetts, is a doctoral candidate in medical engineering/medical physics at the Harvard-MIT Division of Health Sciences and Technology. He has a SM in electrical engineering & computer science from MIT, and an ScB in physics from Brown University.

His research is focused on the development of radiology systems for rural and low-income communities. He was awarded the 2018 John R Cameron Young Investigator award by the American Association of Physicists in Medicine (AAPM).

Assessing Fit and Filtration of N95 Respirators following ^{60}Co Gamma Irradiation

Avilash Cramer

Harvard-MIT Division of Health Sciences and Technology

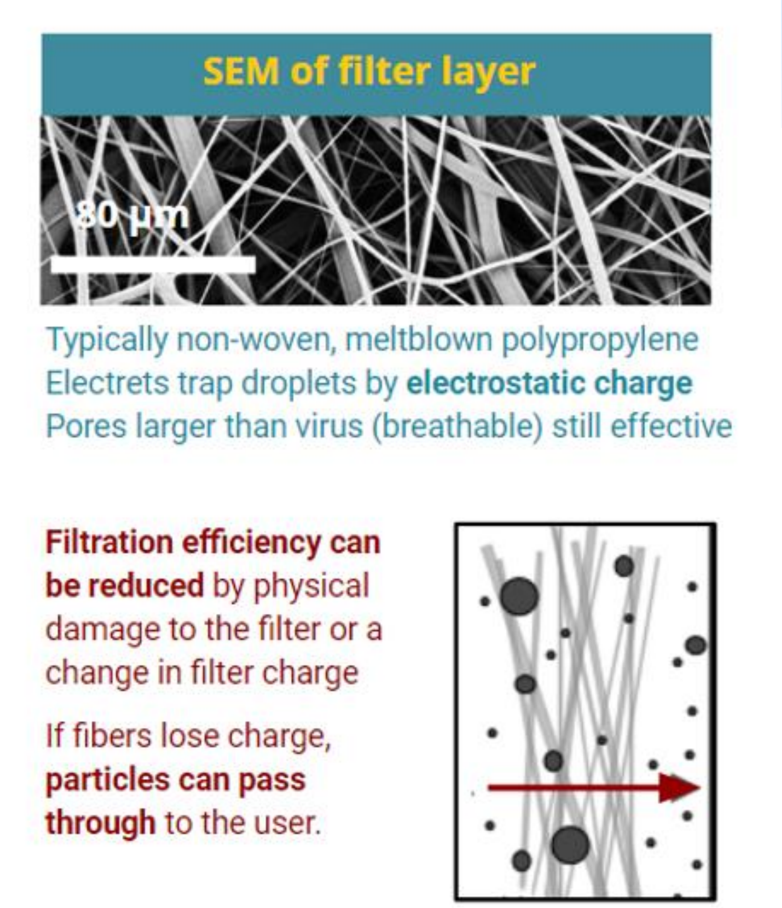
avilash@mit.edu

Coronavirus in Massachusetts

- Population of Massachusetts: 6.9 million
- As of 16 May:
  - 70,000 covid-19 cases
  - 3,500 currently hospitalized
  - 1,000 in intensive care units (50% of capacity)
  - 5,500 **confirmed** deaths from covid-19; true excess mortality is much higher
- **Drastic shortages in Personal Protective Equipment (PPE), especially N95 respirators**

How does an N95 work?

- **Intended to be disposable**
- Tight mesh of fibers 1um apart
- Fiber layer is electrostatically charged
- **Mechanism of action is electrostatic, not mechanical**



SEM of filter layer

Typically non-woven, meltblown polypropylene
Electrets trap droplets by **electrostatic charge**
Pores larger than virus (breathable) still effective

Filtration efficiency can be reduced by physical damage to the filter or a change in filter charge

If fibers lose charge, **particles can pass through** to the user.

Gamma radiation

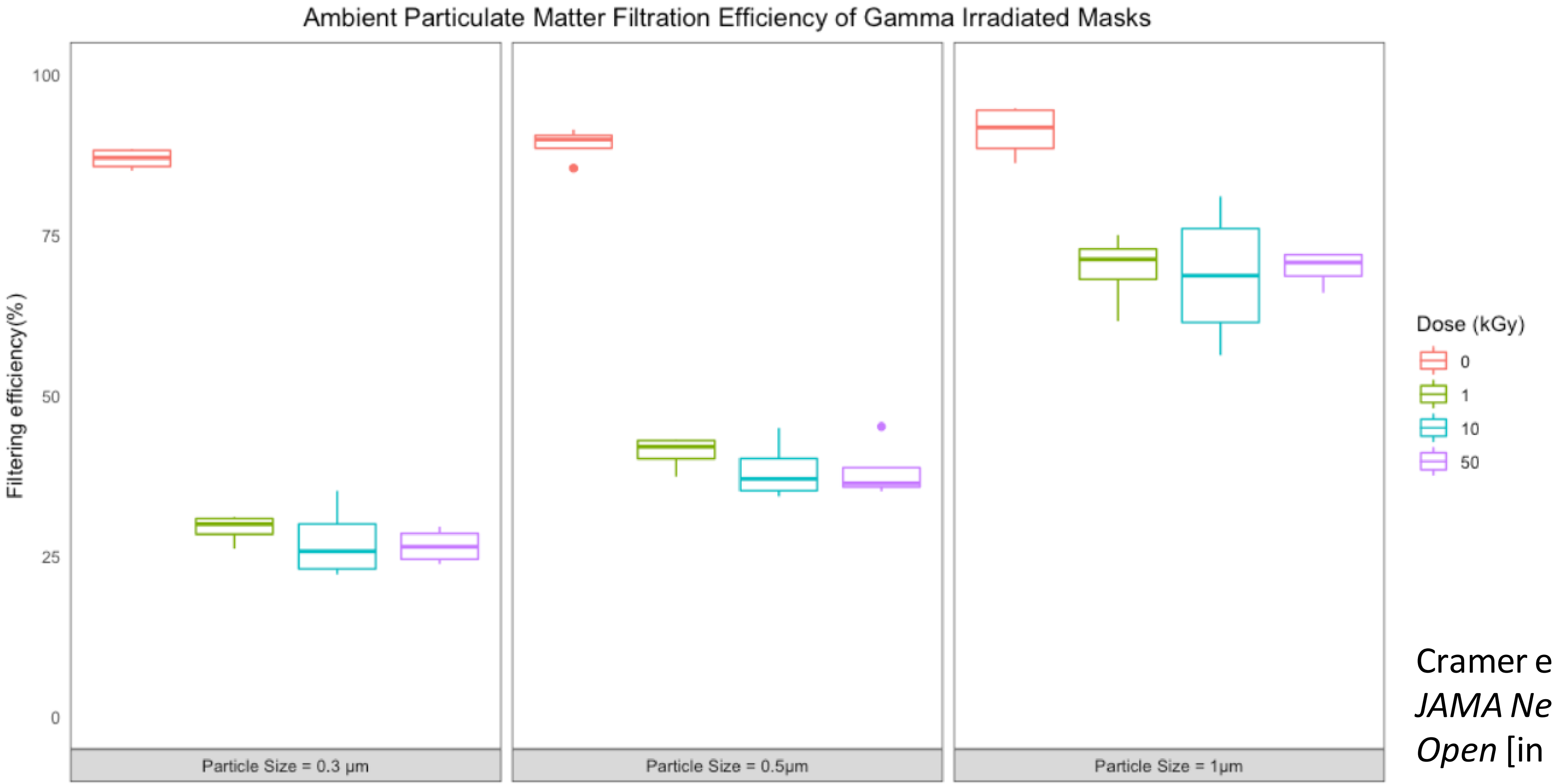
- 3M 1805, 1905, and 8210 respirators
- ^{60}Co ~= 1.3 MeV gamma
- 2.2 kGy/hr
- Tested 0, 1, 10, and 50 kGy dose; 10 kGy considered sterilizing
- All tested masks passed fit testing

^{60}Co source

Filter sample inserted in duct

Ambient particulate matter

Optical particle counter

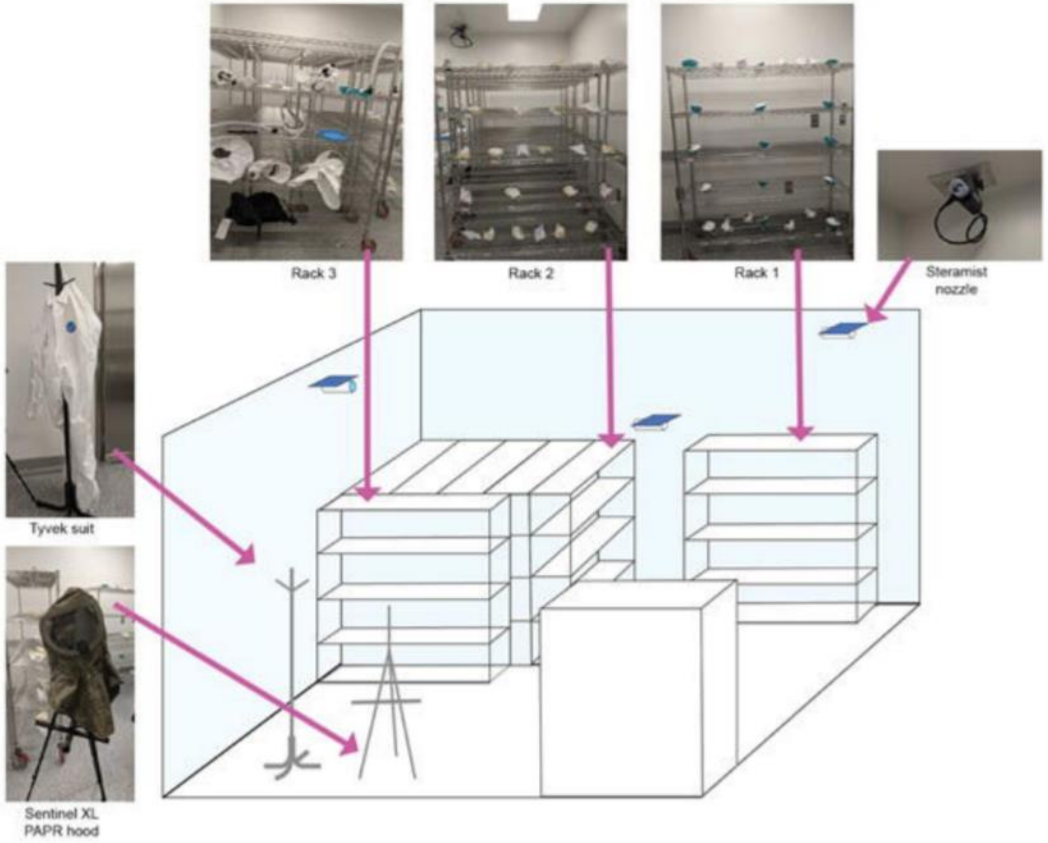


Cramer et al, 2020
JAMA Network Open [in press]

- **Dramatic decrease in filtration performance, especially at 300 nm**

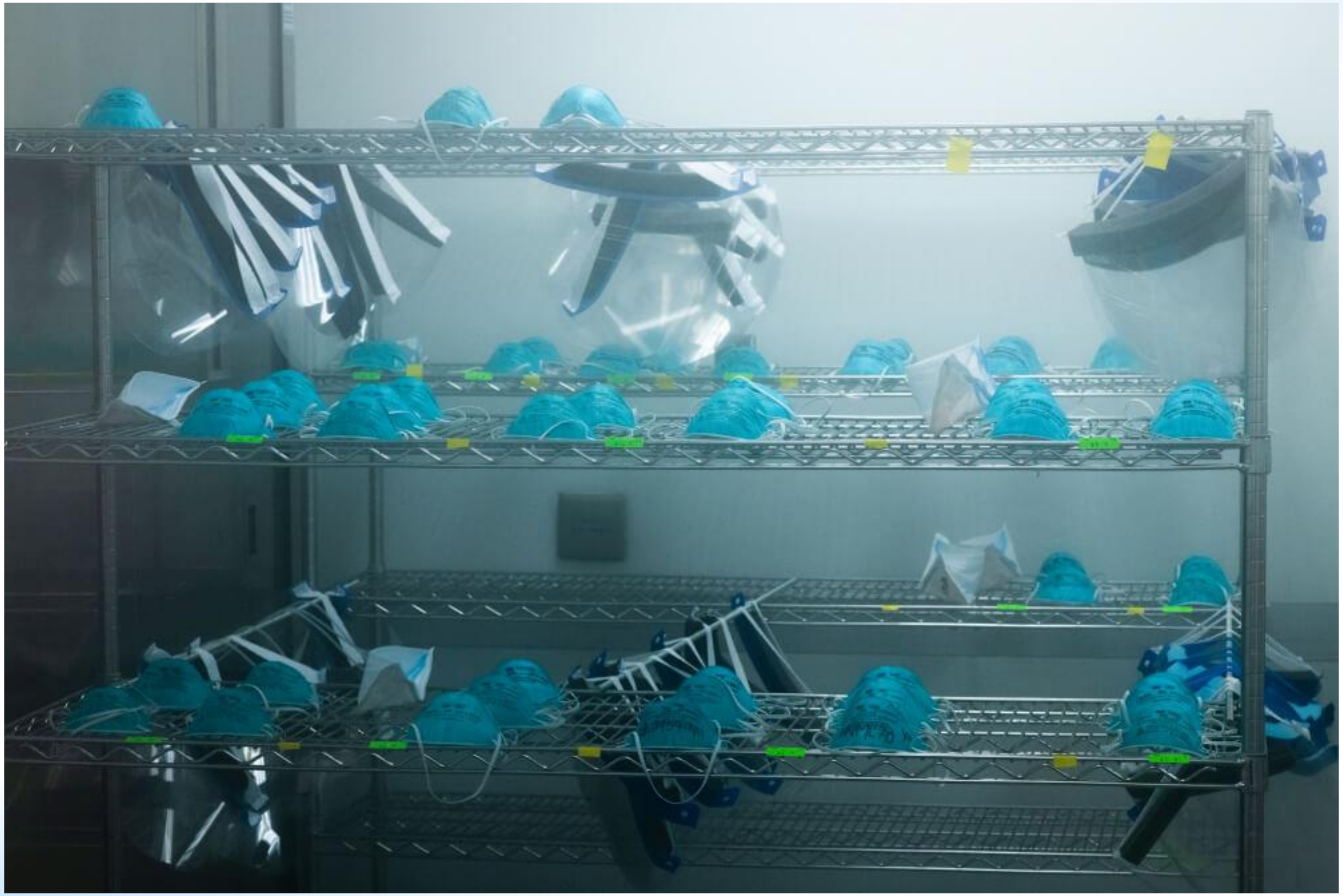
Ionized hydrogen peroxide (iHP)

- Inside of Dana-Farber Cancer Institute
- 100 minute cycle, can fit hundreds of respirators
- Currently doing 500/week, could do up to 2000/day
- No effect on filtration at up to 10 cycles; straps usually break before then anyways



Cramer et al, 2020
BMJ OEM [under review]

Ionized Hydrogen Peroxide (iHP)



Conclusions

- When testing N95 respirators, both fit and filtration need to be tested
- Gamma radiation damages the electrostatic filtering of N95 respirators
- Ionized hydrogen peroxide is a viable method of PPE sterilization, and currently in use to re-use hundreds of respirators and PAPRs each week at a local hospital

avilash@mit.edu

Panelist

Luvimina G. Lanuza - Philippines

Ms. Luvimina G. Lanuza, from the Philippines, holds the degrees of Master in National Security Administration (MNSA) from the National Defense College of the Philippines and B.Sc in Chemistry from the Far Eastern University of Manila, Philippines.

She has 38 years of experience in the field of radiation processing and high-dose dosimetry. She is currently the Head of the Irradiation Services Section from the Nuclear Services Division of the Philippine Nuclear Research Institute (PNRI). She is also the Facility Manager of the PNRI Gamma and Electron Beam Irradiation Facilities.

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International Atomic Energy Agency

DOST DOST-PNRI DOST- ITDI

PROSPECTS OF RADIATION STERILIZATION OF PPE AND VENTURI VALVES IN THE PHILIPPINES

LUVIMINA G. LANUZA
PHILIPPINE NUCLEAR RESEARCH INSTITUTE
DEPARTMENT OF SCIENCE AND TECHNOLOGY
Webinar:“COVID-19 Pandemic: Radiation Sterilization of PPE”
21 May 2020

PPEs

Arrangement of PPE as irradiated at the Electron Beam Irradiation Facility (topview)

Shoe cover

Tyvek suit

Arrangement of PPE as irradiated at the Ob-Servo Sanguis Irradiator (top view)

3M N95 mask

Surgical mask

KN95 mask

Estimated Throughput of Electron Beam Irradiation Facility and Ob-Servo Sanguis Self-shielded Gamma Irradiator

Irradiation Facility	Sample	Quantity per Pack (Suggested packing)	No. of samples that can be irradiated/ day
Electron Beam Irradiation Facility	Tyvek Suit	1 pc. (three-fold)	8,772
	N-95 masks (3M -Model 8210)	2 pcs	73,100
	KN95 masks	1 pc.	23,392
	Surgical masks	1 pc.	26,316
	Cover shoes	1 pc.	6,120 pairs
Ob-Servo Sanguis Self-shielded Gamma Irradiator	Tyvek Suit	1 pc. (three-fold)	6
	N-95 masks (3M -Model 8210)	8 pcs.	80

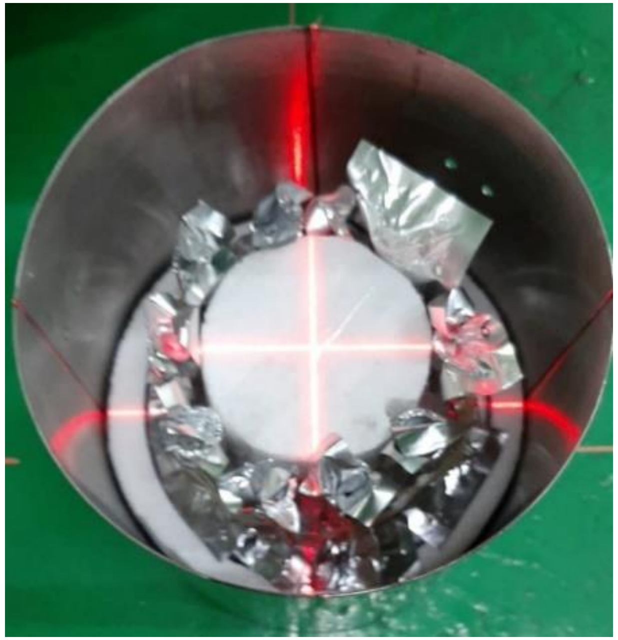
Irradiation of 3D-printed Venturi Valves

- Irradiation of Venturi Valves using Ob-servo Sanguis self-shielded gamma irradiator of DOST-PNRI:
    - to determine material compatibility to radiation

      (DOST-ITDI)
    - to establish the sterilization dose (DOST-PNRI)

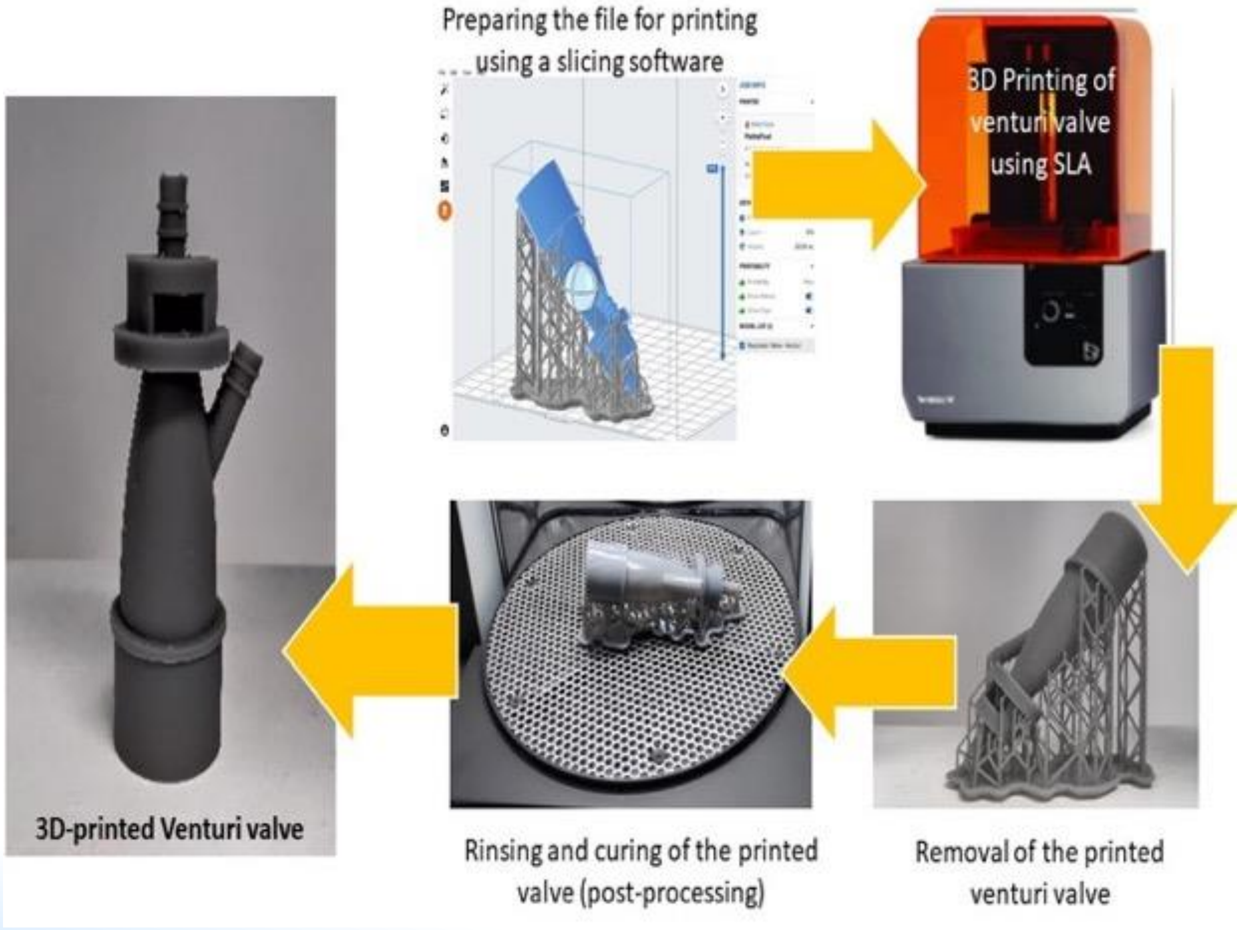
Operator loading the samples in the Ob-Servo Sanguis Gamma Irradiator

Venturi Valves



Venturi valve samples (packed in aluminum foil) inside the sample chamber - top view

3D printed venturi valve



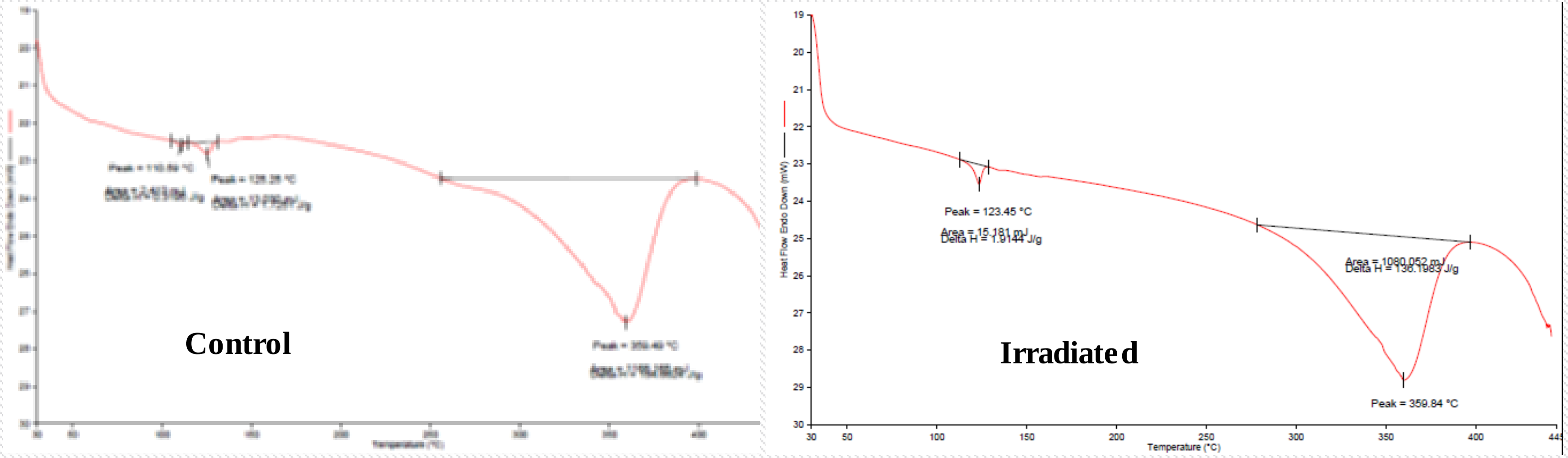
Design, Slicing and 3D-Printing Process of Venturi Valve (DOST-ITDI)

The 3D design of the respirator valve was sourced online in the form of .stl file ready for slicing or build preparation. Slicing was done using Formlabs' Preform slicer. A photocurable resin was used for Stereolithography (SLA).

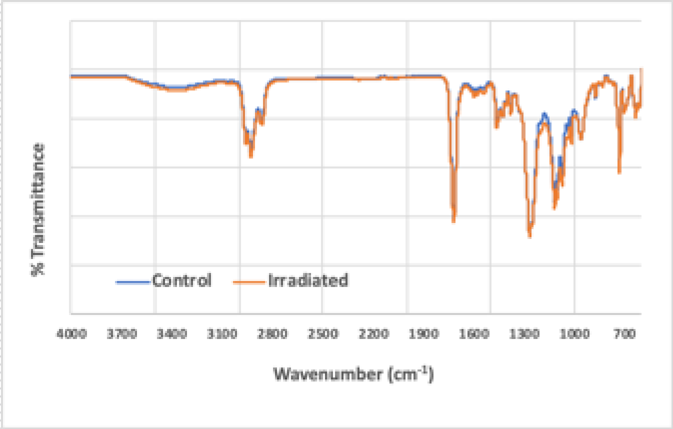
Figure 1. shows the general procedure for the 3D printing of venturi valves using SLA. Printing time for one venturi valve is 4 hours and 43 minutes, consuming around 21 mL of 'Formlabs Grey resin'. After printing, the valve was soaked in isopropyl alcohol for 30 minutes to remove the residual resin, which was then expelled from the walls of the valve using an air compressor. The valve was soaked again for 15 minutes in isopropyl alcohol before drying. The last step was the UV-curing of the printed valve at 60^{o}C for 1 hour.

Summary of results

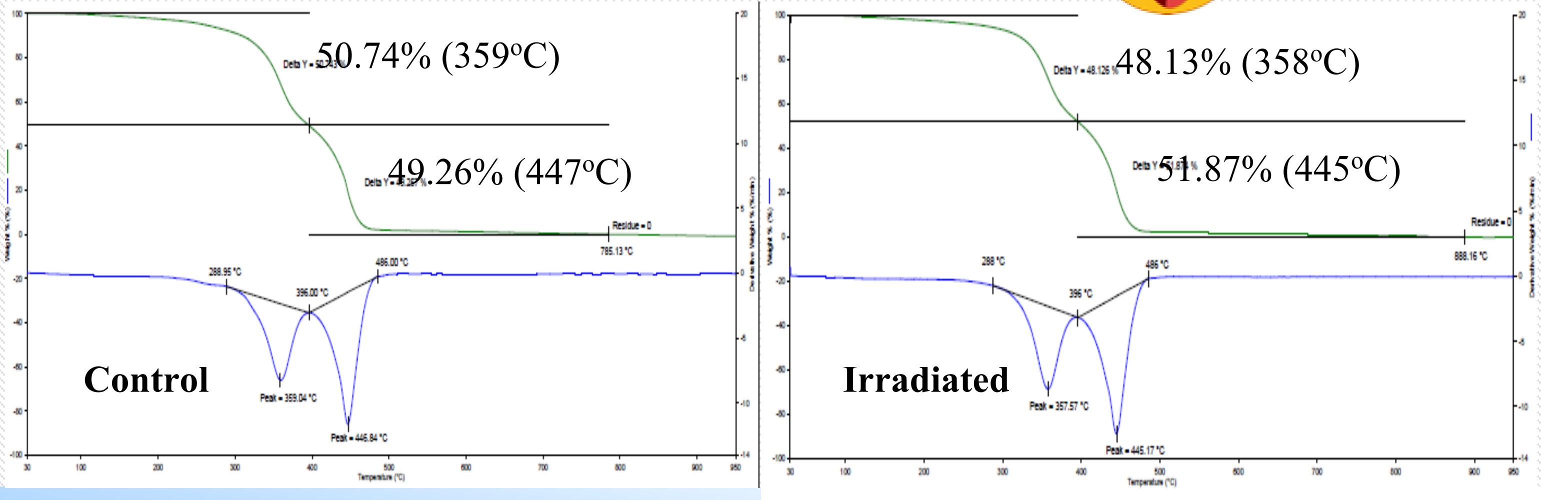
DSC Curves



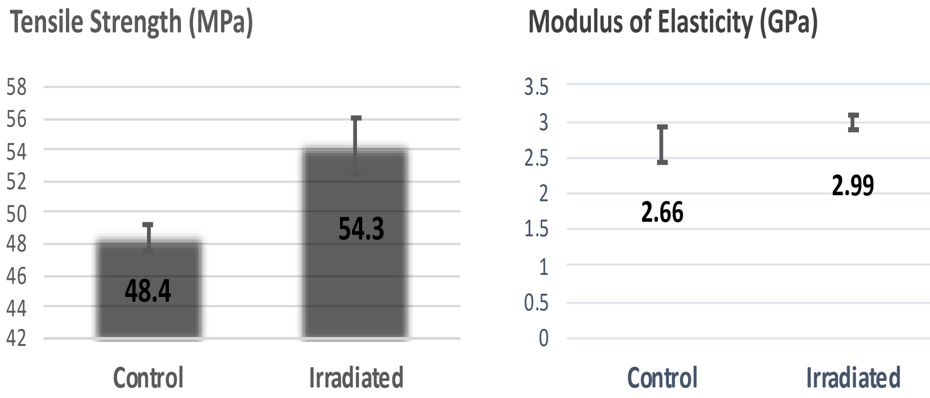
FTIR



TG-DTG Curves



Tensile Strength & Modulus of Elasticity



The irradiated samples has higher results (due to the induced curing effect caused by irradiation).

Conclusion

- PPEs (except respiratory masks) can be irradiated at the new Ob-Servo Sanguis gamma irradiator and EB Irradiation Facility provided they are packed as recommended and dose setting studies had been completed.

- FTIR spectra on venturi valves showed no significant degradation after gamma irradiation. DSC and TG-DTG curves showed that thermal properties of the material was not much affected and tensile test results showed no significant mechanical degradation after irradiation. From these results, venturi valve is radiation compatible up to a dose of 50 kGy

- After finishing the dose setting studies, irradiation of venturi valve at Ob-Servo Sanguis gamma irradiator can be routinely done, at an estimated volume of 80 pieces per batch

Panelist

Pablo Vasquez - IPEN/Brazil

Mr Pablo Vasquez, from Brazil holds the degrees of Ph.D. in Chemical Engineering and Nuclear Technology from the Washington University in St. Louis, US and the University of São Paulo, Brazil, M.Sc. in Nuclear Technology from the University of São Paulo, Brazil and B.Sc. in Chemical Engineering from the National Polytechnic School, Brazil.

He has extensive experience on the field of development and applications of the radiation processing technology for health, industry and environment, having actively participation with the IAEA as a speaker and consultant on related projects. He is currently the R&D and Innovation Manager in the Radiation Technology Center at the Nuclear and Energy Research Institute (IPEN) and professor in the Nuclear Technology Applications Graduation Program at the University of São Paulo (USP), Brazil.

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Development of methodologies for decontamination, reuse and improvement of the properties of respiratory protective equipment using ionizing radiation – preliminary results

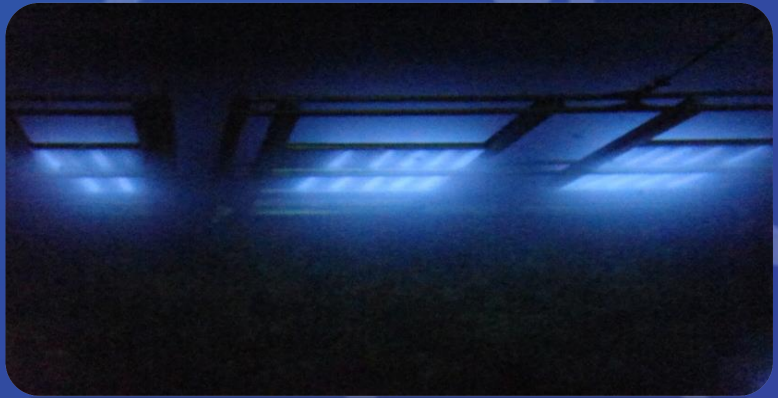
P.A.S. VASQUEZ[1], F. MORAIS[3], F.S. LIMA[2], P. S. SANTOS[1], O. MORAES[4], P. ARTAXO[3], V.M. JOHN[3], M.L.E. NAGAI[3], M.J.A. OLIVEIRA[1], L.H. CATALANI[3], Y. KODAMA[1], L. OTUBO[1]

1 Nuclear and Energy Research Institute -IPEN/CNEN, Sao Paulo, Brazil

2 Technological Research Institute – IPT, Sao Paulo, Brazil

3 University of São Paulo – USP, Sao Paulo, Brazil

4 Santa Catarina Hospital - HSC, Sao Paulo, Brazil



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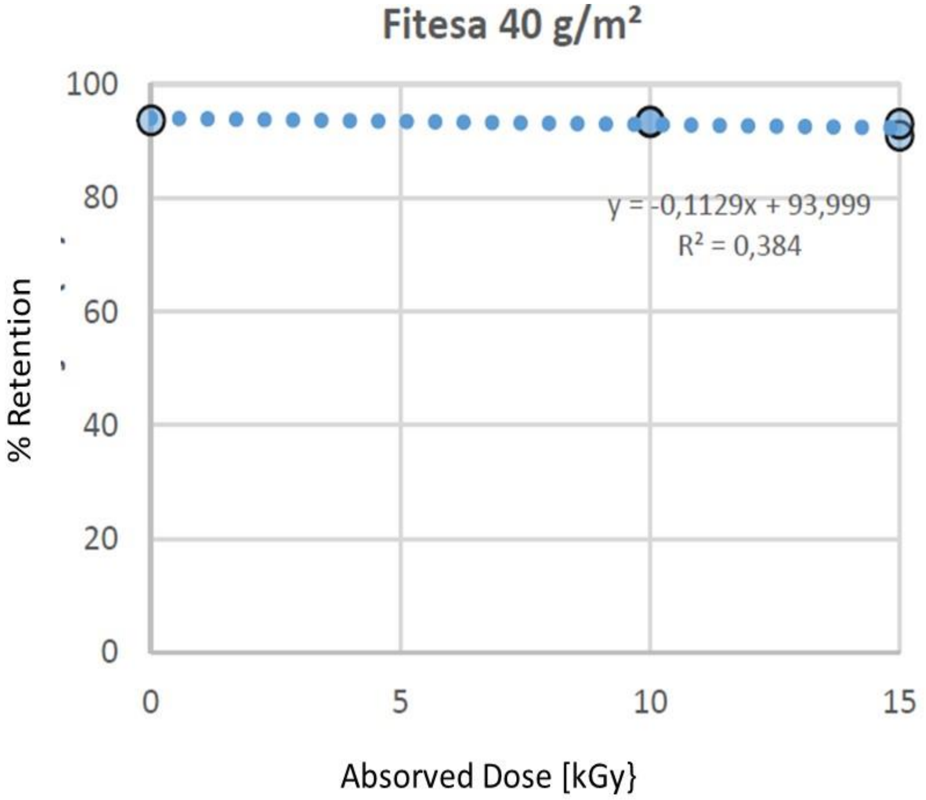
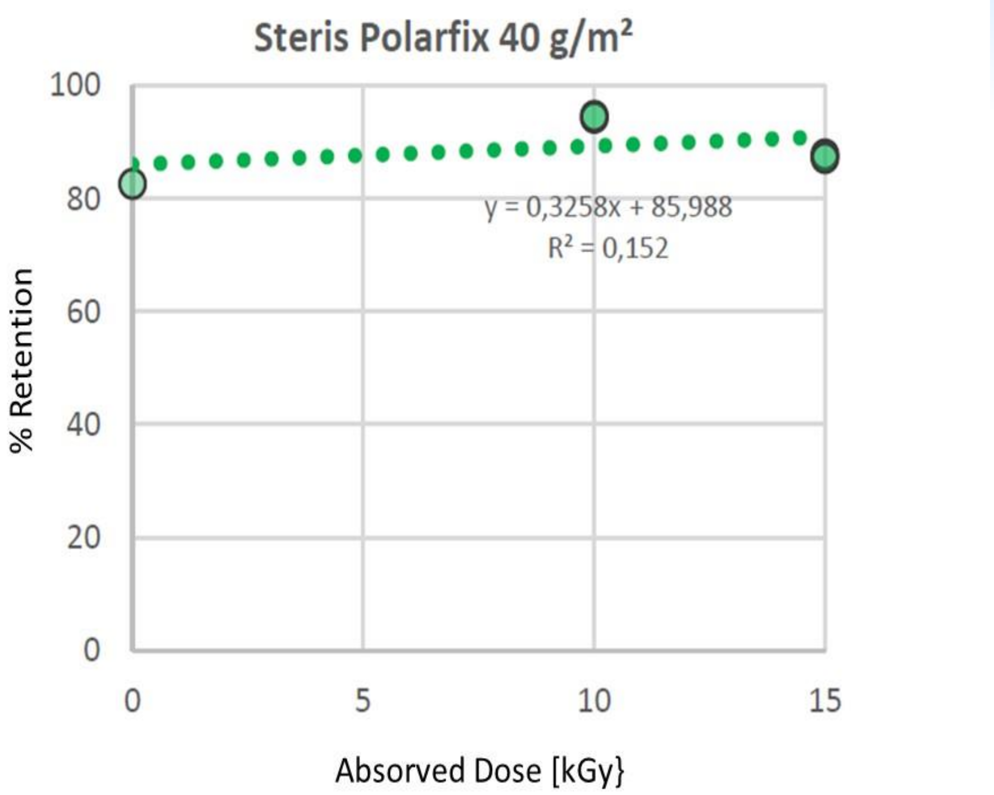
• What is the main purpose of irradiation (sanitisation for non-controlled hand-manufacturing environment)

- In the pandemic scenario **amid shortages of personal protective equipment (PPE)**, Brazilian non-governmental organizations, foundations, private initiative and volunteers, **created social inclusion projects** where seamstresses, informal professionals and prisoners began to make hand-manufacturated masks using meanly **cloth / textile (e.g. cotton)** and **polypropylene nonwoven fabric (surgical PP).** Some of the masks are donated to needy communities in the country others are destined for essential professionals (hospitals, police, army).
- However, **a) non-controlled hand-manufacturing environment**, different from clean industrial processes, can induce biological contamination in the produced masks and **b)** from previous experience, users from poor communities are **not expected to wash the cloth masks before use**.
- In this sense, **gamma irradiated PPE (cloth/textile and nonwoven PP)** was studied and characterized meanly to ensure the **filtration efficiency remained stable** and processing conditions have been established.
- Results shown that gamma irradiation guarantees the hand-manufacturated masks are **totally sanitized (disinfected)** and offers **safe conditions for use** the PPE without leaving chemical toxic residues. It is important to note that in **these materials there are no electrostat processes**.

Nonwoven PP filtration efficiency tests





Which institutions are involved in this solidarity project? (agreements)

- **Nuclear and Energy Research Institute – IPEN** (Gamma Irradiation and characterization - analytical techniques)

https://www.ipen.br/

- **Technological Research Institute** – IPT (characterization -analytical techniques)
- **INOVA-USP - University of São Paulo –USP** (hand-manufacturing nonwoven PP masks "Respire" project - characterization)

https://inova.usp.br/respire

- **Paraisópolis Residents Union** -"*União dos Moradores e do Comércio da comunidade de Paraisópolis*" **Sewing dreams** –"*Costurando sonhos*" -(hand-manufacturing cloth / textile masks project)

https://pt-br.facebook.com/UniaoParaisopolis/

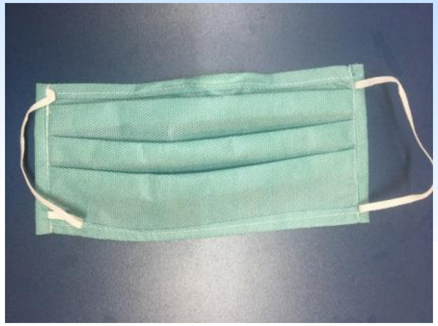
- **Alfaiataria de Negócios, Consultoria em Marketing e Planejamento** /Plan International Brasil – Sylvia Facciolla (hand-manufacturing cloth / textile masks project)

https://plan.org.br/

- "***Prof. Dr. Manoel Pedro Pimentel*" Foundation – FUNAP** (hand-manufacturing nonwoven PP masks project)

http://www.funap.sp.gov.br/site/index.php/noticia/274

Please discus the number of masks manufactured and treated (from the Cooperative and penitentiary)



There are four main projects in which irradiation is being applied:

1. INOVA-USP - University of São Paulo –USP

(i) create a **production model by low-income professionals** (seamstresses) "*Tecido Social*",

(ii) the use of techniques to characterize the materials used for their approval,

(iii) a campaign for the responsible use of PPE for health professionals.

(iv) emergency supply and temporary service for thee two hospitals connected to USP (*Hospital das Clínicas -HC* and *Hospital Universitário-HU*).

Production to the end of July / 2020, a **total of up to 01 (one) million surgical masks (nonwoven PP) for related hospitals**. Irradiated batch sets can reach between **50,000 to 100,000 masks / week.**

IAEA

INOVA.USP
University of São Paulo
Innovation Center

(respire !

IFUSP
Instituto de Física da USP

Tecido Social

POLI USP

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2. Paraisópolis Residents Union -“*União dos Moradores e do Comércio da comunidade de Paraisópolis*” (hand-manufacturing cloth / textile masks “*Costurando Sonhos*” project)

- “***Costurando Sonhos***” **- Seamstresses** from needy communities.

-Estimated total production around **01 (one) million of cloth /textile masks**

-Donation to needy community

-Irradiated batch sets can reach between **15,000 masks / week**

2. Paraisópolis Residents Union -“*União dos Moradores e do Comércio da comunidade de Paraisópolis*” (hand-manufacturing cloth / textile masks “*Costurando Sonhos*” project)

-

Costurando Sonhos

3. Alfaiataria de Negócios, Consultoria em Marketing e Planejamento /Plan International Brasil – Ms. Sylvia Facciolla (hand-manufacturing cloth / textile masks project)

- **Seamstresses, informal professionals, donations, volunteers**, etc.
- Production and irradiation is around **15,000 cloth /textile masks per week**.
- Donation for needy community

3. Alfaiataria de Negócios, Consultoria em Marketing e Planejamento /Plan International Brasil – Ms. Sylvia Facciolla (hand-manufacturing cloth / textile masks project)

4. “*Prof. Dr. Manoel Pedro Pimentel*” Foundation – FUNAP (hand-manufacturing nonwoven PP masks project)

- FUNAP works for the **inclusion and social reintegration of prisoners**, developing their potential as individuals, citizens and professionals.
- Masks manufactured by the national penitentiary system. Every three days worked, inmates have a day of pardon. They also receive re-socialization scholarship equivalent to 3/4 of a minimum wage.
- **Masks for professionals considered essential** (hospitals, police, military etc.)
- Irradiated batch sets can reach **30,000 masks / week**

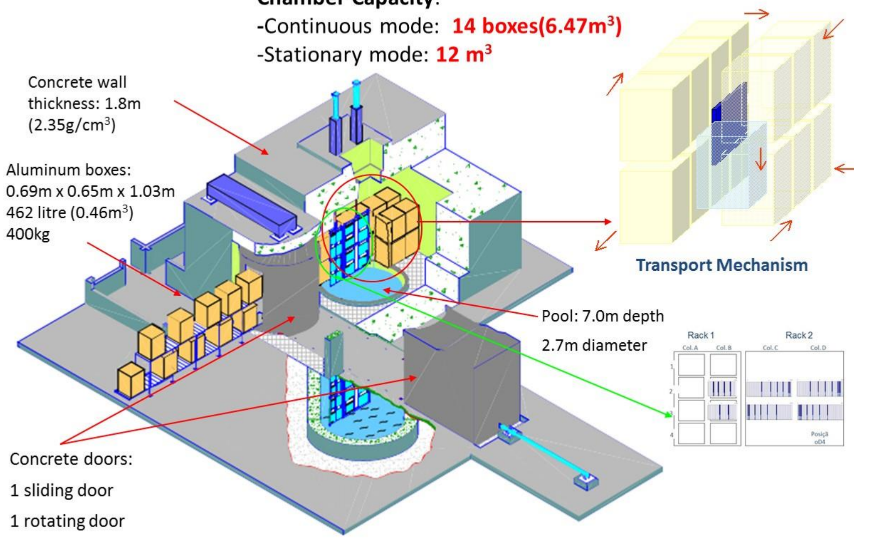
http://www.funap.df.gov.br/coronavirus-presos-vao-produzir-mascaras-de-seguranca/

• Please describe the safety measures in your irradiation facility

- Irradiation facilities in Brazil are controlled by the **National Nuclear Energy Commission -CNEN.**
- Safety and Security standards are strictly applied at **Multipurpose Gamma Irradiation Facility**
- The use of **respiratory masks is mandatory** throughout the work period for both operators and visitors/users.
- Materials are handled with **protective clothes and gloves and a quarantine period** (if possible) is used before handling.
- If possible, an **70% ethanol spray is applied** on the surface of boxes containing the material before irradiation process.
- Distance is kept constantly.

IPEN/CNEN – São Paulo /SP
Capacity: 1000kCi

Chamber Capacity:
-Continuous mode: **14 boxes(6.47m^3)**
-Stationary mode: **12 m^3**



Concrete wall thickness: 1.8m (2.35g/cm^3)

Aluminum boxes: 0.69m x 0.65m x 1.03m 462 litre (0.46m^3) 400kg

Pool: 7.0m depth
2.7m diameter

Concrete doors:
1 sliding door
1 rotating door

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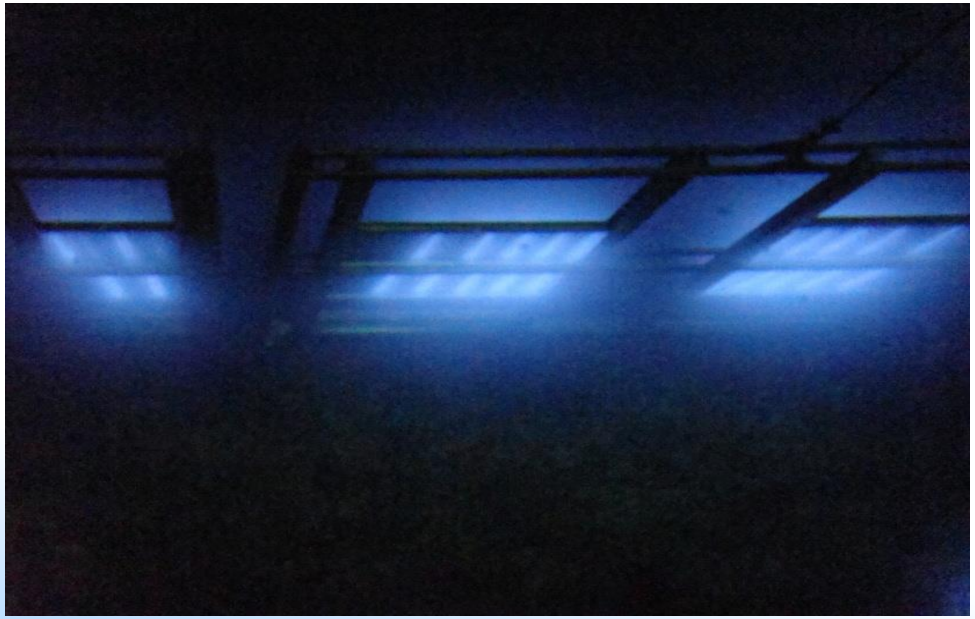


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15 x 337 g
UNIÃO DOS MORADOR
COMÉRCIO DE

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Panelist

Paul Wynne – International Irradiation Association

Paul is a Chartered Accountant. He joined Isotron plc – a UK based international contract irradiation company in 1987 and was part of the management team that expanded the gamma technology base to include electron beam and X-ray during the 90’s.

In 1999/2000 Paul worked in Malaysia to manage the construction of a large gamma irradiation facility. He was involved in the acquisition, and management of Gammaster from 2001 and in 2004 he was a founding director of the International Irradiation Association. Subsequent to an acquisition Paul worked for Synergy Health from 2007. He later managed the construction of sterilisation facilities in China. He was appointed Regional CEO Asia and Africa at Synergy in 2010.

He is now a consultant and is Chairman and DG of IIA.

Section 4 - Prospects

An Industrial Processing Perspective

HONESTY

FEASIBILITY

COMMUNICATION

- Key Questions
- Selecting a Technology
- The Value of Networks

Section 4 - Prospects

Large Volume Industrial Irradiation

QUESTIONS

- What volume requires processing
- What ‘dose’ is required + min and max
- What is the density / packing options
- What is the required turnaround time
- Actions taken to manage the bio-hazard
- Delivery and collection times / form
- Validation plans

Section 4 - Prospects

Technology Options 1

GAMMA

- Globally only 250 gamma facilities
- Most operate at 95-98% utilisation
- Relatively slow - hours not minutes
- Scheduling complexity – dose/density
- Tote, Pallet and Batch

Section 4 - Prospects

Technology Options 2

ACCELERATORS

- Type – High, Medium and Low Energy
- Eb / X-ray – numbers and locations
- Handling systems – Wire v Cart
- Penetration and Density
- Process Speed & Turnaround Times

Section 4 - Prospects

A Global Community

COMMUNICATIONS

- Community – Operators / Suppliers / Universities & Institutes
- Collaborating with Regional & Special Interest Groups
- Connecting with the IAEA
- iia – an integrated networking and communications hub

GENERAL CONCLUSIONS

General Conclusions

- **Ionizing radiation is an effective and established tool to sterilize personal protective equipment** (PPE) that is in high demand during the COVID-19 pandemic, including surgical and hand-made masks. Also seems to be promising for reuse of some items
- **Respiratory masks**, made of melt-blown polypropylene (PP) nonwoven fabric, used as the filtration layer, **are not suitable to be radiation sterilized** because it affects filtration performance (tested in gamma and Ebeam, from 1 to 60 kGy, in air an vacuum)

More information:
Technical Report

STERILIZATION AND REPROCESSING OF PERSONAL PROTECTIVE EQUIPMENT (PPE), INCLUDING RESPIRATORY MASKS, BY IONIZING RADIATION

http://www-naweb.iaea.org/napc/iachem/working_materials/Technical%20Report%20(Mask%20Reprocessing).pdf

Finishing…

- Radiation sterilization has a long and successful time living with us, but we must be scientifically correct when selecting it for new products or new intended uses

- Networking was possible even remotely! (Technical Report, Survey results, and all of you listening to us)

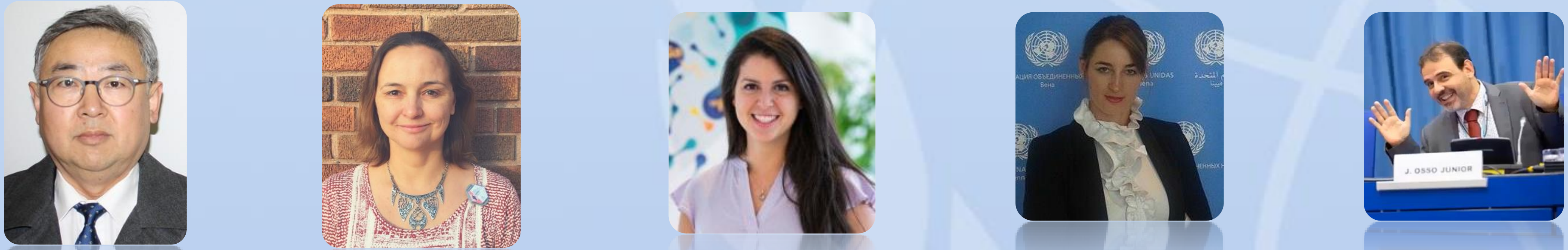
ACKNOWLEDGEMENTS

Panelists

Audience

NAPC: Melissa Denecke, Mark O´Connell and Lucilena Rebelo Monteiro

RPRT Team:



Bum Soo HAN, Valeriia STAROVOITOVA, Julia VERA-ARAUJO, Vojna NGJEQARI, and Joao OSSO-JUNIOR

Q/A SESSION

Thank you!