



2023 Single-Use Pulse Webinar Series

IMPLEMENTATION OF X-RAY STERILIZATION OF SINGLE-USE SYSTEMS: WHAT TO EXPECT

 Thursday, March 9, 2023

 10 – 11:30 AM EST

Presenters

Samuel Dorey, Sartorius

James Hathcock, Pall Corporation

Created in Cooperation With...



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The AdvantaPURE logo features the word "Advanta" in a green, serif font and "PURE" in a blue, sans-serif font. A small "NEWAGE INDUSTRIES" tagline is visible below "Advanta".The Broadley James logo displays the name "Broadley" in a black, serif font above "James" in a blue, serif font.The bürkert logo features the brand name in a blue, lowercase, sans-serif font, with "FLUID CONTROL SYSTEMS" in a smaller, blue, uppercase font below it.The CPC logo includes a blue, stylized circular icon to the left of the letters "CPC" in a black, sans-serif font.The cytiva logo consists of a green, stylized circular icon followed by the word "cytiva" in a black, lowercase, sans-serif font.The DUPONT LIXEO logo features the word "DUPONT" in a red, sans-serif font above "LIXEO" in a black, sans-serif font, with a blue and green stylized icon between the two words.The Entegris logo features a red, stylized circular icon above the word "Entegris" in a black, sans-serif font.The Millipore Sigma logo displays the words "Millipore" and "Sigma" in a blue, sans-serif font, stacked vertically.The Nordson MEDICAL logo features a blue, stylized circular icon to the left of the word "Nordson" in a blue, sans-serif font, with "MEDICAL" in a smaller, black, sans-serif font below it.The PALL logo consists of the word "PALL" in a blue, sans-serif font, enclosed within a blue oval, with "PALL CORPORATION" in a smaller, black, sans-serif font below it.The PENDOTECH logo features the word "PENDOTECH" in a blue, sans-serif font, with the tagline "Adding Value To Your Process" in a smaller, pink, sans-serif font below it.The RENOLIT logo features a black and white stylized icon above the word "RENOLIT" in a black, sans-serif font, with the tagline "Rely on it." in a smaller, black, sans-serif font below it.The SAINT-GOBAIN logo features a colorful, stylized graphic of a building or structure above the words "SAINT-GOBAIN" in a blue, sans-serif font.The SARTORIUS logo displays the word "SARTORIUS" in a black, sans-serif font.The solvias logo features the word "solvias" in a blue, sans-serif font, with a green and yellow stylized icon to the right.The ThermoFisher SCIENTIFIC logo features the words "ThermoFisher" in a red, sans-serif font above "SCIENTIFIC" in a black, sans-serif font.

Implementation of X-ray for Single-Use

Implementation Ramp-Up, Capacity & Risks

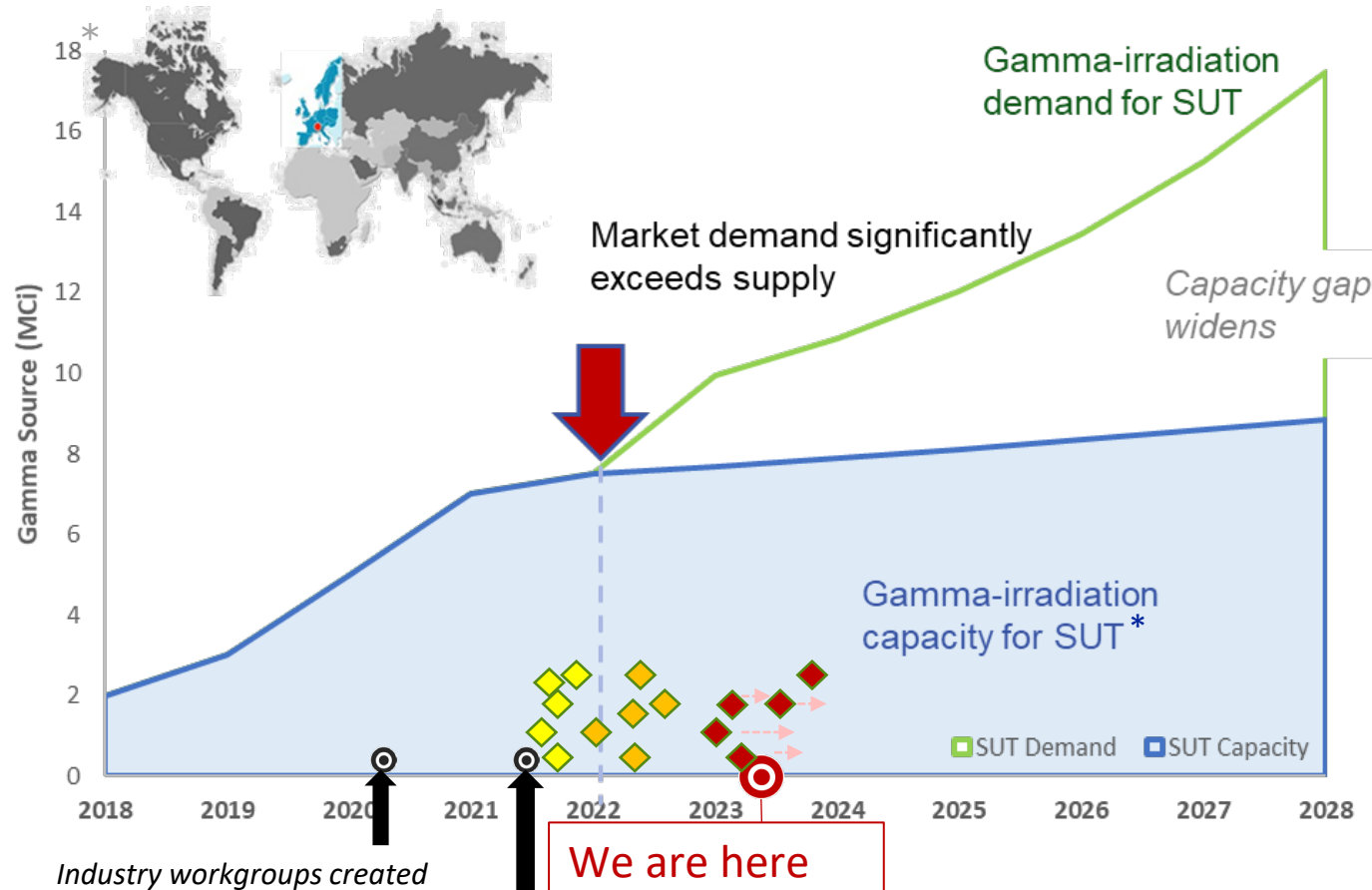
BPSA X-ray Qualification Testing Paper

Regulatory Perspectives

Staying Current

Implementation Ramp-Up

Contract Irradiation Capacity Bottle-Neck for Single-Use



2021 BPSA White Paper. X-ray Sterilization of Single-Use Bioprocess Equipment: Part I – Industry Need, Requirements, and Risk Evaluation.

Timelines

- ◆ Integrators Pre-change Notification Issued
- ◆ Change Notifications Issued
- ◆ Implementation Targets

Challenges

- 🏛️ Regulator Uncertainty
- 🏭 Capacity Buildout

Mapping of Irradiation Sites and Key Risks

- Opening Dates
 - Steris, Daniken (Switzerland) - open
 - Steris, Venlo (Netherland) - open
 - Steris, Libertyville (USA) – June 2023 (TBC)
 - Steris, Chomburi (Thailand) – Summer 2023 (TBC)
 - Steris, Suzhou (China) – planned
 - Others in pipeline
- Risks: additional delays
- Dose Mapping performed as within gamma sites
- Potential tension to Cobalt-60 supply due to current sanctions

Implementation of X-ray for Single-Use

Implementation Ramp-Up, Capacity & Risks

BPSA X-ray Qualification Testing Paper

Regulatory Perspectives

Staying Current

Sterilization Modality or Technology

Sterilization Modalities

Heat



Chemical



Technologies / Processes

Gamma



X-Ray



Beta / E-beam



**Ionizing
Radiation**

2021 BPSA X-ray Assessment White Paper

Responses to radiation for different polymers intrinsically related to the chemical structures of the polymers

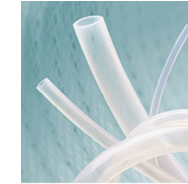
- Focus on polymers with limited irradiation compatibility (worst case)
- Couple material-science assessments with component testing
- Not retest every component.
- Demonstrate existing data packages remain valid for X-ray



Bags & Film



Sensors



Tubing
(TPE,
Silicone)



Filters



Aseptic
Connectors

		Good irradiation compatibility at 50kGy										Limited compatibility at 50 kGy							Poor					
		HDPE	LDPE	PC	PEEK	PEI	PET	PS	PSU	PUE	PVDF	EPDM	Polyamide (Nylon)	PBT	PES	PP	PVC	Silicone	TPE	FEP	PTFE	PEBA	Functionalized Materials	Cellulose
Compatibility with Ionizing Radiation		●	●	●	●	●	●	●	●	●	●	▲	▲	▲	▲	▲	▲	▲	▲	◆	◆	-	-	▲
Single-Use Components	Connectors			●				●	●						●			●	●					
	Containers (bags, bottles, carboys)		●																					
	Ports on containers	●																						
	Sensors	●	●	●	●				●						●	●		●	●					
	Tubing															●								
	Filters					●	●				●		●	●	●	●		●		●	●		●	
	TFF devices	●								●			●		●			●						
	Fittings and molded parts	●		●	●						●					●	●		●					●
	Pumps, check valves											●				●			●		●			
	Needles				●											●								
	O-rings, Gaskets, Seals		●									●						●				●	●	
	Packaging		●														●				●	●		

Materials Impact Assessment

Material Assessments

- **FTIR.** *Chemical fingerprint*
- **DSC.** *Heat flow characteristics (melting temperature, crystallinity)*
- **TGA.** *Change in mass with thermal decomposition*
- **Mechanical.** *(components dependent)*
- **DMA.** *Viscoelasticity (components dependent)*

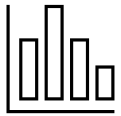
1st investigation level to assess X vs G impacts

120 Material Assessments		Good irradiation compatibility at 50kGy										Limited compatibility at 50 kGy							Poor			Functionalized Materials		Cellulose		
		HDPE	LDPE	PC	PEEK	PEI	PET	PS	PSU	PUE	PVDF	EPDM	Polyamide (Nylon)	PBT	PES	PP	PVC	Silicone	TPE	FEP	PTFE				PEBA	
Compatibility with Ionizing Radiation		●	●	●	●	●	●	●	●	●	●	▲	▲	▲	▲	▲	▲	▲	▲	◆	◆	-	-	-	-	▲
Single-Use Components	Connectors			●				●	●						●			●	●							
	Containers (bags, bottles, carboys)		●																							
	Ports on containers	●												●				●								
	Sensors	●	●	●	●				●				●		●	●		●	●							
	Tubing																●	●	●							
	Filters					●	●				●		●	●	●	●		●		●	●		●			
	TFF devices	●								●				●	●	●		●						●		
	Fittings and molded parts	●		●	●						●					●		●								
	Pumps, check valves											●				●			●		●					
	Needles				●											●										
	O-rings, Gaskets, Seals										●							●				●				
	Packaging		●													●					●	●				

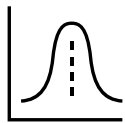
Key outputs



The paper reflects multiple types of testing, data presentation and ways to evaluate the results



A review of multiple datasets, from different components, materials and suppliers, offers a robust holistic perspective



In addition to the materials and component qualification supporting X-ray, other evaluation criteria have been openly shared within the BPSA working group, but were outside the scope of this data-based review



It shows the hypothesis mentioned in WP1 is right: same irradiation physics and thus equivalent impact

Part II. Representative Qualification Data

Draft pending BPSA board review

X-Ray Sterilization of Single-Use Bioprocess Equipment. Part II – Representative Qualification Data

Published by:

Bio-Process Systems Alliance (BPSA)
1400 Crystal Drive
Arlington, VA 22202

Authors & Data Contributors

Maria Bollensen	CPC
Monica Cardona	<u>MilliporeSigma</u>
Samuel Dorey	Sartorius
CD Feng	Broadley-James
James Hathcock	Pall
Roger Hendrick	DuPont
Nicole Hunter	Watson-Marlow Fluid Technology Solutions
Lan Luo	Pall
Timo Neuman	<u>MilliporeSigma</u>
Lise Tan-Sien-Hee	DuPont
Nick Troise	<u>PendoTECH</u>
Andrew Trolie	<u>NewAge</u>
Gabrielle Wilson	<u>Saint Gobain</u>

Acknowledgements

We want to thank the following people for their contribution to the development and review of this guide.

- Executive Summary
- Temperature and Activation with Radiation Processing
- Physical and Functional Component Data
- Chemical Tests
- Materials Assessments
- Biological Tests
- Assembly Integrity
- Conclusions and Next Steps
- Appendices

Part II. Representative Qualification Data

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Acknowledgements

We want to thank the following people for their contribution to the development and review of this guide.

	Primary MOC	Materials	Physical	Functional	Chemical	Biological
Biocontainer						
Flexsafe® bag (S80 film)	PE's/EVOH	●	●	●	●	●
Connector						
Lynx® S2S	PSU, Sil	●	●	●	●	●
AseptiQuik® AQG	PC, PPSU, PE, PES, Sil	●	●	●	○	○
Filter						
Kleenpak™ EKV Capsule	PP, PES, EPDM	●	●	●	●	●
Sensor						
PendoTECH Single Use Pressure Sensor™	PSU	●	●	●	■	■
BroadleyJames pH Sensor	Glass, PEEK, EPDM, Si(Pt)	○	○	●	○	○
Tubing						
Pumpsil®- Bioprene®- Pureweld®	Si(Pt)-TPV-SEBS	●	●	●	⦿	⦿
AdvantaFlex APAF	TPE	●	●	●	●	○
Liveo™ Pharma Tubing	Si(Pt)	●	●	●	■	●
C-Flex® 374 Tubing	TPE	●	●	●	⦿	●
SaniTech® Ultra-C Tubing	Si(Pt)	●	●	●	⦿	●

Temperature and Activation Associated with Radiation Processing



Tested materials irradiated at 55-80 kGy show no reports of significant activation



Average maximum temperatures experienced during gamma irradiation were 35-45°C vs 30-40°C with X-ray irradiated samples at 50±5kGy

Overall assessment

Materials
Ethylene propylene diene monomer (EPDM)
Polyamide (PA)
Polybutylene terephthalate (PBT)
Polycarbonate (PC)
High-density polyethylene (HDPE)
Low-density polyethylene (LDPE)
Neodymium-containing magnet alloy
Polyether ether ketone (PEEK)
Polyethylene (PE)
Polyethylene terephthalate (PET)
Polyethylene terephthalate glycol (PETG)
Polyolefin (POE)
Polypropylene (PP)
Polysulfone (PSU)
Polyvinyl chloride (PVC)
Polyvinylidene fluoride (PVDF)
Stainless steel (clamp)
Styrene-butadiene copolymer (SBC)
Silicone (Si)
Thermoplastic elastomer (TPE)

Physical and Functional Component Data



Chemical Tests



Materials Assessments



Biological Tests



Implementation of X-ray for Single-Use

Implementation Ramp-Up, Capacity & Risks

BPSA X-ray Qualification Testing Paper

Regulatory Perspectives

Staying Current

Regulator Engagement & Alignment

FDA ETT CDER Engagement ① Dec 2021 ② Sept 2022

- | X-ray appears new concept
- | Need cross functional expertise & data
 - | Physicists, Single-use SMEs, Pharma manufacturers
- | Good vibes
 - | Sterility assurance ✓
 - | Functionality assessment ✓
- | Continued engagement
 - | Extractables (low/high pH)
 - | Case Studies
- | MHRA/EMA Engagement Critical

1

Qualification of X-Ray Sterilization for Single Use Systems in Pharmaceutical Processing (FDA ETT Engagement)

2

Qualification of X-Ray Sterilization for Single Use Systems in Pharmaceutical Processing (FDA ETT Engagement)

James Hathcock, PhD
Sr. Director of Regulatory & Validation Strategy
Pall Corporation & BPSA Task Force Lead

Adam Whaites
Global Sterility Assurance Director
Cytiva Life Sciences & Chair of The Irradiation Panel

Samuel Dorey, PhD
Principal Scientist of Materials and Irradiations, Product Development
Sartorius Stedim Biotech & BPSA Task Force Lead

Ping Wang, PhD
Director of Research & Development
Janssen, Pharmaceutical Companies of Johnson and Johnson

Ken Wong
Critical Material Management Lead
Sanofi S.A.

Tom Oliver
Sr. Process Engineer
BioMarin Pharmaceutical

Thomas Kroc, PhD
Applications Physicist and Head of the Neutron Irradiation Facility
Fermi National Accelerator Laboratory (Fermilab). US DOE.

CDR Patric Klotzbuecher-Cruz
Senior Biomedical Engineer
DHHS/BARDA/PCI/PVPCR Branch

Lance Garrison, PhD
Domestic Alternative Technology Portfolio Manager
DOE/National Nuclear Security Agency/Office of Radiological Security

Robert Huffman
Supply Chain Management Lead
DHHS/BARDA/Division of Pharmaceutical Countermeasures Infrastructure (PCI)

Joseph Figlio
Chief of Pandemic Vaccine Preparedness Capabilities & Readiness (PVPCR) Branch
DHHS/BARDA/PCI

Frank Flores
Drug/Vaccine Supply Chain Manager
Tunnell Government Services supporting DHHS/BARDA/PCI/PVPCR Branch

Anabela Marca
EMA Liaison to FDA

Maria Jesus Alcaraz Tomas
Regulatory Science & Innovation Task Force, Supply & Availability of Medicines & Devices. EMA.

Brian Dooley
Pharmaceutical Quality Office. EMA.

Sept 8, 2022

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Transitioning from Gamma to X-ray

- **ISO 11137** “Sterilization of Healthcare Products” **covers** gamma and **X-ray**
 - ✓ No change to dose window (*transfer of dose*)
 - ✓ Dose mapping required for new radiation sources/sites
 - ✓ Sterility dose audits with X-ray will demonstrate continued effectiveness
 - ✓ Activation studies demonstrate no meaningful radioactivity
 - ✓ No impact to sterility assurance level (SAL)

“Dose mapping studies are well-described in ISO11137 and are to be coordinated by the SUS integrator for each unique irradiation site to verify the dose received for their product during routine manufacturing is between the minimum and maximum dose.

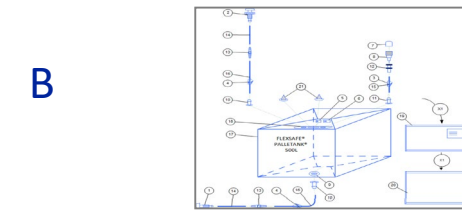
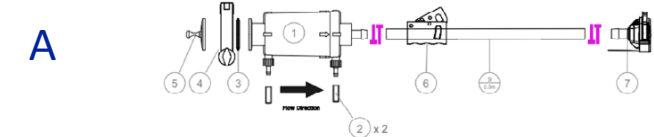
Sterility dose audits, also well described in ISO 11137 are also expected to be performed by the integrator to demonstrate the continued effectiveness of the ionizing irradiation process over time.”

Transitioning from Gamma to X-ray

- **Fundamental physics** of gamma and x-ray are equivalent
 - ✓ Gamma to X-ray is not a “modality” change (*heat, radiation, gas*)
- **Sponsor risk-assessment** based on
 - ✓ Irradiation physics understanding
 - ✓ Evaluation of wide range of representative materials
 - ✓ Limited testing to “verify” equivalence, but not revalidate
 - USP <665> “moderate risk” testing to assess leachables risk
- Case study Risk Assessments for post-approval changes

Case Study Risk Assessment & Regulatory Notification Action

Case Study	Gamma mentioned in approved filing
Case A: Single-use filtration assembly in final sterilizing-grade filtration step of monoclonal antibody product	No
Case B: Single-use storage bag assembly for mixing and/or storage of formulation buffer	No
	Yes
Case C: Low risk applications (<u>e.g.</u> associated with or upstream of clearance steps)	No



Authors Note: The assessments included in this document represent the consensus opinions of recognized subject matter experts in the pharmaceutical industry who have been actively engaged in industry groups and review panels focused on risk assessment and qualification of X-ray. This includes three team members currently employed in related risk assessment roles at different pharmaceutical manufacturers, and two team members from different single-use providers. Authors names and affiliations are indicated where allowed per company policy. As part of this process additional subject matter experts within companies have been consulted and existing regulatory filings reviewed to ensure in good faith and to the best of our ability that these case studies and assessments are largely representative of those expected in 2023 and beyond. These opinions represent those of the authors, and in most cases have not been formally reviewed and endorsed by their companies or industry organizations in which they participate

Case Study Risk Assessment & Regulatory Notification Action



Case Study	Gamma mentioned in approved filing	Final Risk Determination (Gamma → X-ray)	Regulatory Notification Action	Agency Feedback
Case A: Single-use filtration assembly in final sterilizing-grade filtration step of monoclonal antibody product	No	Low Risk	Annual report	Annual Report*
Case B: Single-use storage bag assembly for mixing and/or storage of formulation buffer	No	Low Risk	Annual report	
	Yes	Low Risk	CBE-30	
Case C: Low risk applications (<u>e.g.</u> associated with or upstream of clearance steps)	No	Low Risk	Non reportable	

*Such changes, where compliant to ISO 11137 including dose mapping and sterility dose audit studies, may be documented in annual product quality review.

Case Study Risk Assessment & Regulatory Notification Action



Case Study	Gamma mentioned in approved filing	Final Risk Determination (Gamma → X-ray)	Regulatory Notification Action	Agency Feedback
Case A: Single-use filtration assembly in final sterilizing-grade filtration step of monoclonal antibody product	No	Low Risk	Annual report	Annual Report*
Case B: Single-use storage bag assembly for mixing and/or storage of formulation buffer	No	Low Risk	Annual report	
	Yes	Low Risk	CBE-30	
Case C: Low risk applications (<u>e.g.</u> associated with or upstream of clearance steps)	No	Low Risk	Non reportable	

In Scope SUS & Applications

- ✓ Formulation buffer mixing & storage
- ✓ Final sterilizing filtration
- ✓ Many inherently low risk applications involving wide range of materials

Not Yet in Scope

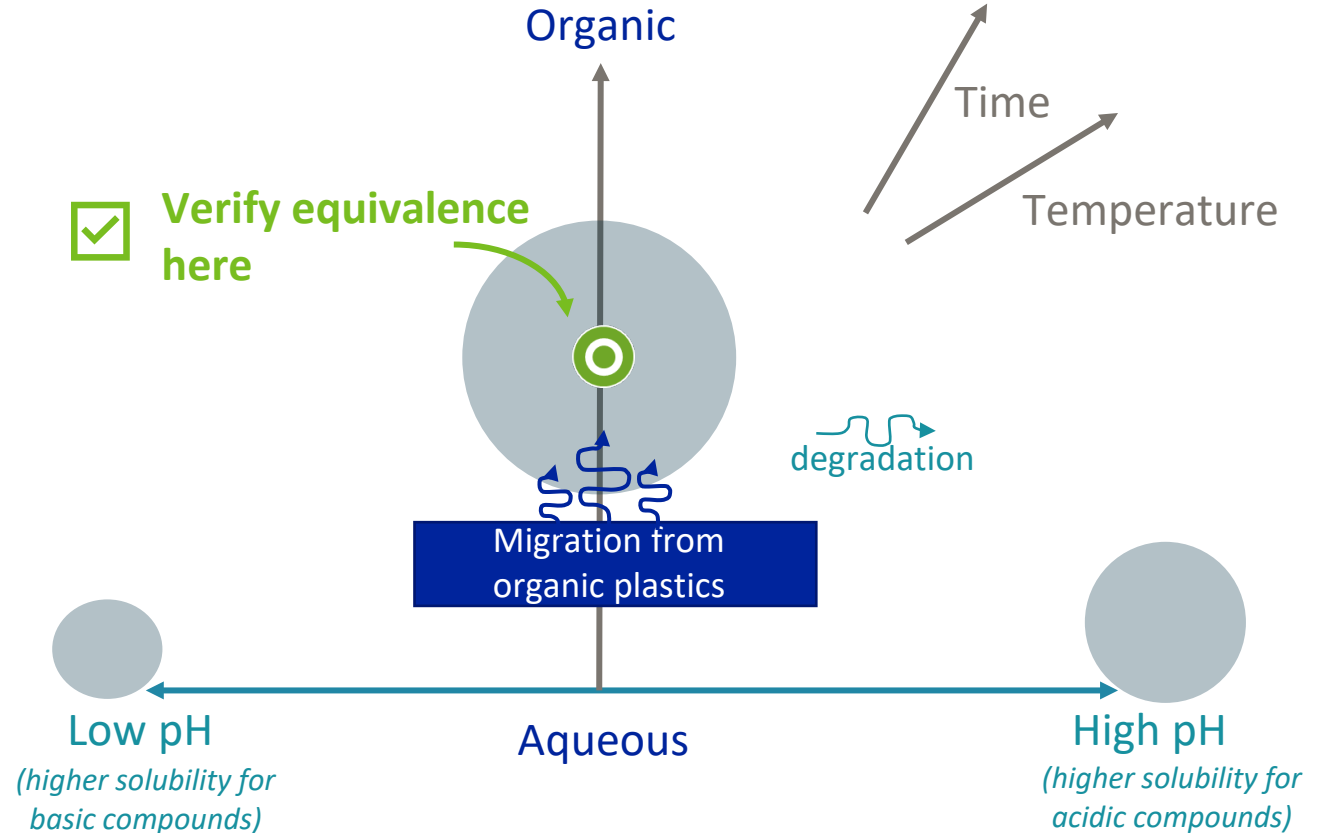
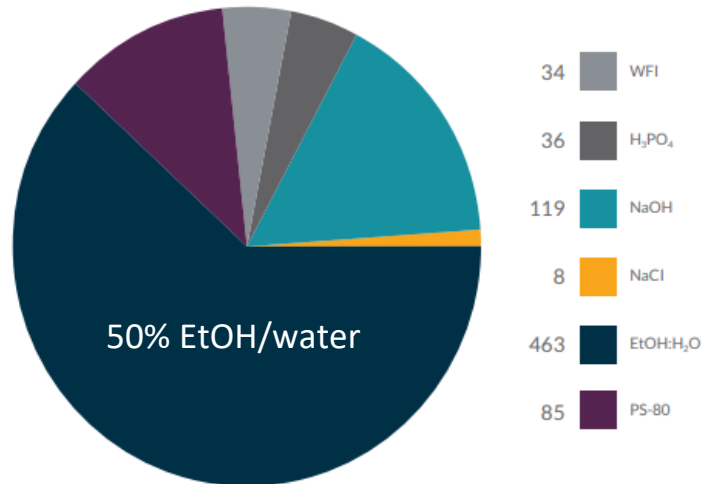
- ✗ Final filling
- ✗ BDS storage
- ✗ Container closure (*not SUS*)

** will likely be implemented at future date*

Rationale for <665> Moderate Risk

50% EtOH/water extraction profile (referred to as <665> expanded baseline testing)

Distribution of unique extractables by solvent



USP <665> Moderate risk testing of representative materials, coupled with materials testing, **VERIFIES** our understanding of the irradiation physics that **X-ray is equivalent to gamma** for single-use materials. The **existing E&L risk assessment remains valid for X-ray**.

Proof-of-concept data (low pH, high pH, high organic) for worst-case components confirm no unexpected effects related to X-ray.

ETT Engagement on X-ray Qualification Expectations for Single-Use Bioprocess Systems



Key points and aligned positions



Sterility
assurance

1. ISO 11137 approach including activation, dose mapping of new X-ray sites, and sterility dose audits sufficient to justify no impact to sterility assurance level (SAL). [A]



Categorization
of changes

2. A sponsor risk assessment based on irradiation physics, materials impact assessment, limited component “verification” testing, and knowledge of the drug manufacturing process is appropriate for transition from gamma to X-ray [B]
3. The case studies and recommended regulatory notification actions (*non-notifiable, annual review, CBE-30*) appear reasonable [B]
4. Whether CBE-30 (vs Annual review) is expected for post-approval changes of filings that mention “gamma”, but the overall risk determination is “low”[B]



USP <665>
Moderate Risk
(Level B)

5. USP <665> “Moderate” risk extractables testing of representative components is suitable to “verify” equivalence, and that existing E&L assessment remains valid (i.e. no impact to E&L.) [C]



Other groups

6. While CDER and CBER agree on points above during meeting, official notes from CBER still pending

Regulatory Perspectives & Feedback

FDA ETT Engagement ① Dec 2021 ② Sept 2022

Executive Summary

ETT Engagement on X-ray Qualification Expectations for Single-Use Bioprocess Systems

1 Executive Summary

Given the urgency to qualify X-ray as an alternative to Gamma for irradiation of single-use systems (SUSs), clear alignment is needed among suppliers, pharmaceutical manufacturers, and regulators on expectations for transition & commercial implementation. On September 8, 2022, a small industry team consisting of members of BioPhorum and BPSA, BARDA and subject matter experts met with the FDA/CDER/Emerging Technologies Team (ETT), including observers from CBER and EMA, to socialize and advocate for the positions published in the 2021 BPSA white paper on X-ray [1], and address concerns expressed by regulators during a prior, December 2021 Type C meeting with the ETT. Specifically, these concerns focused on the need for (i) examples of how sponsors would assess, categorize, and notify authorities when implementing a change, as well as (ii) proof-of-concept extractables data for representative worst-case components which verify that there are no unexpected effects under low pH, high pH, or high organic content. The package included (i) the follow-up Type C meeting request which identified key questions on which agency feedback was desired; (ii) the May 2021 BPSA whitepaper; (iii) a recently finished & to-be published technical paper demonstrating the comparability of X-ray and Gamma irradiation physics; (iv) the December 2021 CDER/ETT Type C meeting minutes; (v) a report consisting of 3 primary examples of post-approval changes and additional supporting rationale for the BPSA-recommended approach to extractables & leachables verification testing; and (vi) a general letter of support for the risk-based approach to assessment, verification, and notification of changes from BioPhorum. Following a detailed, interactive discussion on September 8, formal meeting minutes were received from the agency on September 20, 2022. The FDA's summary and description of the consensus met were consistent with the understanding of the industry participants, were regarded as highly positive to the advancement of the initiative, and aligned with the industry's need for practical, risk-based approaches to the transition to X-ray sterilization.

The key questions and responses in the attached meeting minutes address those posed in the meeting request. A brief overview of the key points and aligned positions is below.

A. Sterility assurance

Sterility assurance concerns around transfer of dose from gamma to x-ray may be addressed per ISO 11137 [2] [3]. Specifically, (i) sterility assurance levels may be considered independent of the source-of photon-based irradiation, as established according to ISO 11137-2; (ii) the x-ray minimum dose may be substantiated through sterility dose audit experiments as described in ISO 11137-2, and (iii) dose mapping studies for each process shall establish that the minimum and maximum dose requirements are achieved by operating within established process settings.

The comments also note that if there is a need to increase the irradiation dose range compared to what was validated for a Gamma sterilization process, then additional studies would be warranted. This case, although worthwhile to consider in the hypothetical, is not expected to manifest with transfer from Gamma to X-ray. Regardless, dose mapping studies will confirm that pre-established dose ranges remain unchanged in transitioning processes.

B. Categorization of changes

Post approval changes that follow the requirements of ISO 11137, and are deemed to be low risk as per the biomanufacturer's assessment may be submitted as part of the Annual Product Quality Report (APQR). This applies to changes that may be used in critical applications such as (A) final, sterilizing-grade filtration assemblies, (B1) formulation buffer mixing assemblies, (B2) applications in which "Gamma irradiation" may have been specifically identified in applicable regulatory filings, or (C) assemblies used in inherently low-risk applications distant to the patient and final drug product.

Meeting Minutes: ETT and BARDA (with Pall Corporation and partners)

ock, PhD, Sr. Director of Regulatory & Validation Strategy
ion & BPSA Task Force Lead
y, PhD, Principal Scientist of Materials and Irradiations,
velopment
lim Biotech & BPSA Task Force Lead
hD, Director of Research & Development
maceutical Companies of Johnson and Johnson
ritical Material Management Lead, Sanofi S.A.
Sr. Process Engineer, BioMarin Pharmaceutical
; PhD, Applications Physicist and Head of the Neutron
ility, Fermi National Accelerator Laboratory (Fermilab), US

is, Global Sterility Assurance Director, Cytiva Life Sciences
re Irradiation Panel
lotzbuecher-Cruz, Senior Biomedical Engineer,
DA/PCI/PVPCR Branch
on, PhD, Domestic Alternative Technology Portfolio
E/National Nuclear Security Agency/Office of Radiological

nan, Supply Chain Management Lead,
DA/Division of Pharmaceutical Countermeasures
; (PCI)
, Chief of Pandemic Vaccine Preparedness Capabilities &
VPCR) Branch, DHHS/BARDA/PCI
Drug/Vaccine Supply Chain Manager, Tunnell Government
supporting DHHS/BARDA/PCI/PVPCR Branch

- Anabela Marca, EMA Liaison to FDA (invited by BARDA)
- Maria Jesus Alcaraz Tomas, Regulatory Science & Innovation Task Force, Supply & Availability of Medicines & Devices, EMA (invited by BARDA)
- Brian Dooley, Pharmaceutical Qualify Office, EMA (invited by BARDA)

• All Meeting
summary and
minutes
available

Implementation of X-ray for Single-Use

Implementation Ramp-Up, Capacity & Risks

BPSA X-ray Qualification Testing Paper

Regulatory Perspectives

Staying Current

Recent Publications

Arthur Charlesby

- <https://doi.org/10.1016/B978-1-4831-9776-0.50007-3> (1960!)

Fermilab

- <https://doi.org/10.1016/j.radphyschem.2022.110702> (2023)

Team Nablo

- <https://doi.org/10.1016/j.radphyschem.2020.109282> (2021)
- <https://doi.org/10.1016/j.radphyschem.2021.109505> (2021)
- [Supplementing Gamma Sterilization – BioProcess](#) (2022)
- [InternationalBioProcess International \(bioprocessintl.com\)](#) (2022)
- <https://doi.org/10.3389/fchem.2022.888285> (2022)

Sartorius

- <https://doi.org/10.1039/D1CC02871E> (2021)
- <https://doi.org/10.1002/btpr.3214> (2021)
- <https://doi.org/10.1016/j.ijpharm.2023.122677> (2023)
- https://dc.engconfintl.org/sut_v/55/ (2022)

Pall

- https://dc.engconfintl.org/sut_v/54/ (2022)
- *Biotechnology Progress (Grzelak et al., in press)* (2023)

Activation

- <https://doi.org/10.2345/0899-8205-55.s3.17> (2021)

Miscellaneous

- <https://doi.org/10.1016/j.radphyschem.2007.01.014> (2007)
- <https://doi.org/10.1016/j.radphyschem.2022.109999> (2022)

Recent Conferences

Single-Use Technologies V Building The Future (Marseille, France, March 2022)

- <http://engconf.us/conferences/biotechnology/single-use-technologies-v-building-the-future/>

Kilmer (Athens, Greece, June 2022):

- [Kilmer Conference](#)

ICARST (Vienna, Austria, August 2022):

- [News: Second International Conference on Applications of Radiation Science and Technology \(ICARST-2021\) | IAEA](#)

IARC (Sept 2022)

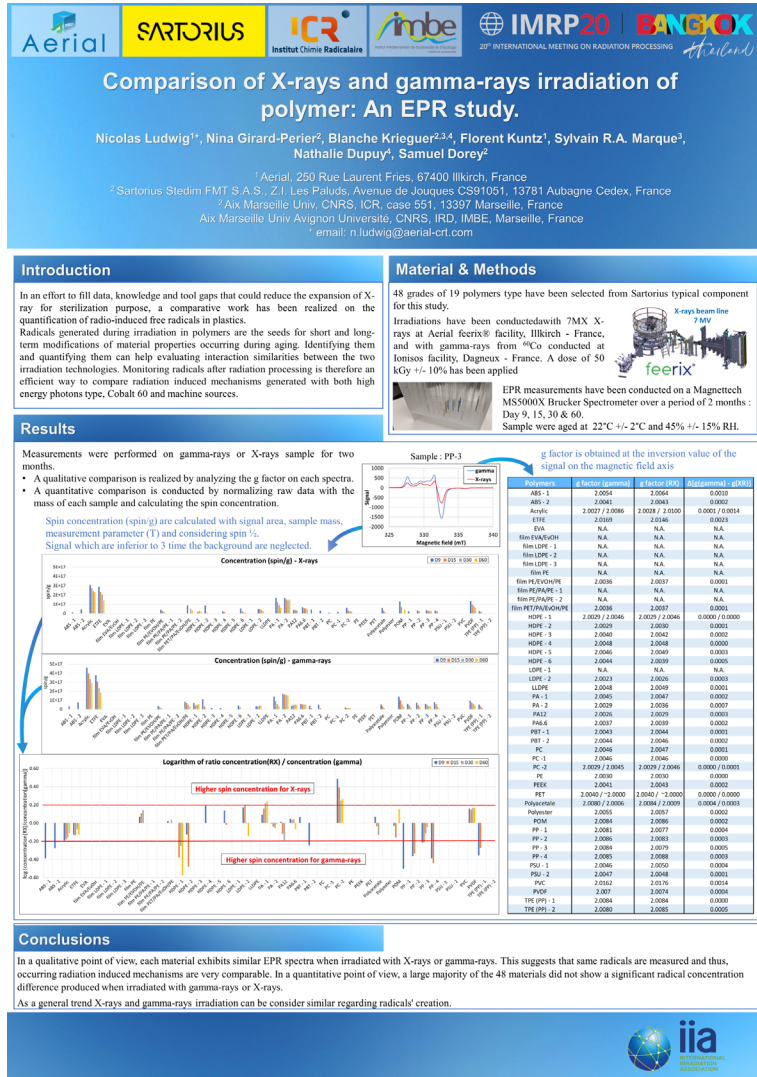
- [Medical Device Sterilization Workshop \(videos online\)](#)

IMRP (Nov 2022) :

- [International Meeting on Radiation Processing \(imrp-iaa.com\)](#)

To be continued in 2023

Insights in Materials Impact Assessment

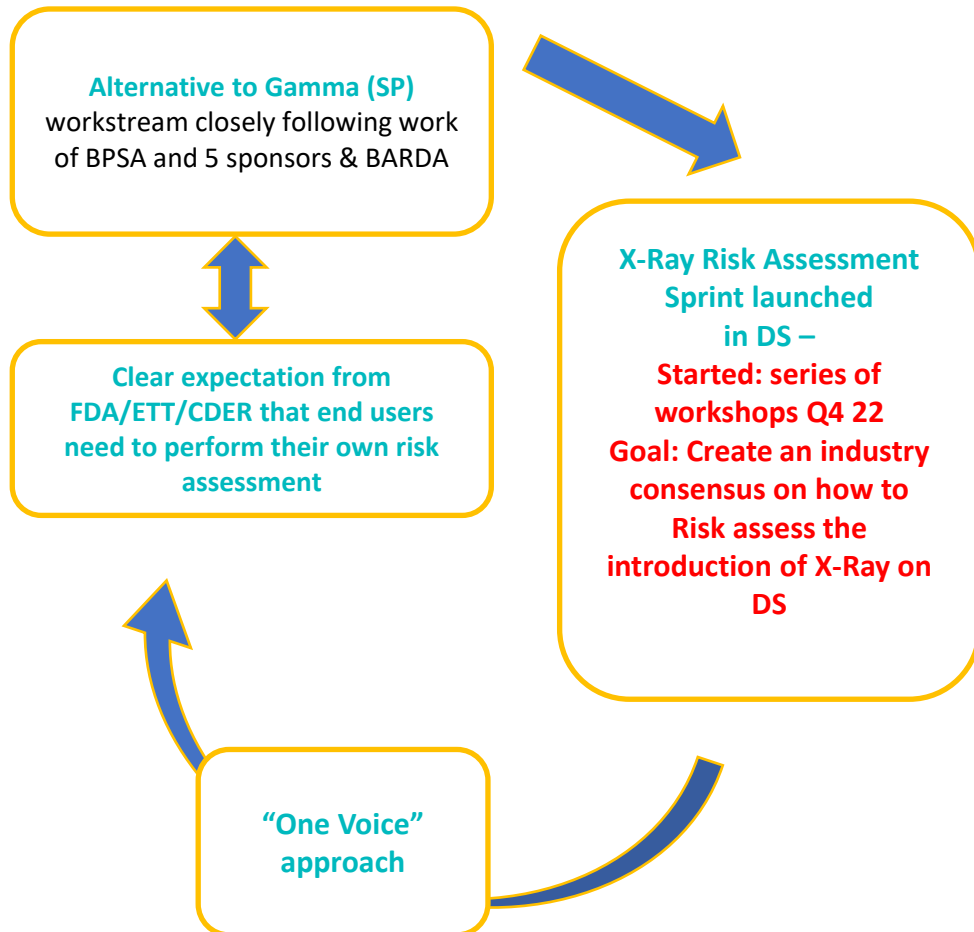


- Radiation interaction effects between matter and Gamma- & X-ray investigated
 - Radicals tracked by EPR (Electron paramagnetic resonance or electron spin resonance (ESR)) spectroscopy
 - Same nature of radicals and equivalent quantity after gamma and X-ray irradiation
- Key interaction outputs equivalent after gamma and X-rays

BioPhorum X-Ray Sterilization Risk Assessment Sprint Workshop



Sharing questions & understanding



The team are aligned on what we want to deliver

Want to reach an industry consensus while embracing the viewpoints of all stakeholders (not every company has the same approach to RA)

Clear decision to focus on low/medium risk (common approach by all biomanufacturers and suppliers) to first implement and to further assess the high risk applications

Consensus approach in preparation; if not, different approaches can be reported to regulatory

X-ray implementation on low/medium risks in 2023 and in 2024/2025 for high risks

ASTM Workshop E55/E61

Radiation Processing for the Pharmaceutical and BioPharmaceutical Industries Training Workshop, May 8-9, 2023

- The objective of this workshop is to enhance the knowledge and understanding of the radiation process and critical requirements needed for the sterilization of components and finished products using radiation technologies
- [Radiation Processing for the Pharmaceutical and BioPharmaceutical Industries Training Workshop \(eventscloud.com\)](https://eventscloud.com)
- This workshop is powered by the ASTM E61 International Workshop on Radiation Processing but focused on and tailored for the individuals supporting the pharmaceutical and biopharmaceutical industries



Registration Open

Thank You BPSA X-Ray Committee!



Kirsten Strahlendorf, Sanofi Pasteur
Board Sponsor

Samuel Dorey, Sartorius
James Hathcock, Pall
Committee Co-Chairs

Committee Participants

Janmeet Anant, MilliporeSigma
Ken Baker, AdvantaPure/NewAge
Nick Troise, PendoTECH
Dennis Annarelli, PendoTECH
Amit Bhatt, Merck
John Murphy, Merck MSD
Andrew Trolio, AdvantaPure/NewAge
Monica Cardona, MilliporeSigma
Timo Neumann, Merck Millipore
Samuel Dorey, Sartorius Stedim FMT
Chad Kratochwill, Entegris

Charlotte Massy, GSK
CD Feng, Broadley James
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Noel Long, Cytiva
Rafael Rodriguez, Cytiva
Jeff Carter, Cytiva
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Paul Calverly, Sterigenics
Jeffrey Noyes, Steris
Deepak Patil, Steris
Cody Wilson, IBA
Ariana Gleisberg, Thermo Fisher
Nicole Hunter, Watson Marlow
Gabrielle McIninch, St Gobain
Max Blomberg, Meissner
Roger Hendrick, Dupont
Lan Luo, Pall

Questions & Discussion



Implementation Ramp-Up, Capacity & Risks

BPSA X-ray Qualification Testing Paper

Regulatory Perspectives

Staying Current

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