The Effects of Gamma Shadowing

The Risk of Using Metal Parts in Single-Use Bioprocessing Systems

Gamma irradiation is a highly effective and widely used method of sterilization for single-use bioprocessing systems. The process does not generate heat or moisture, which makes it ideal for sensitive aseptic applications such as culture-media production, and the filling of sterile APIs and biopharmaceutical products. In addition, its validation procedures are well established, and it can be applied under safe, well-defined parameters.

Despite its effectiveness, gamma sterilization can be subject to interference from certain materials. This interference can cause a phenomenon known as gamma shadowing, which poses a significant risk to aseptic bioprocessing.

What Is Gamma Shadowing?

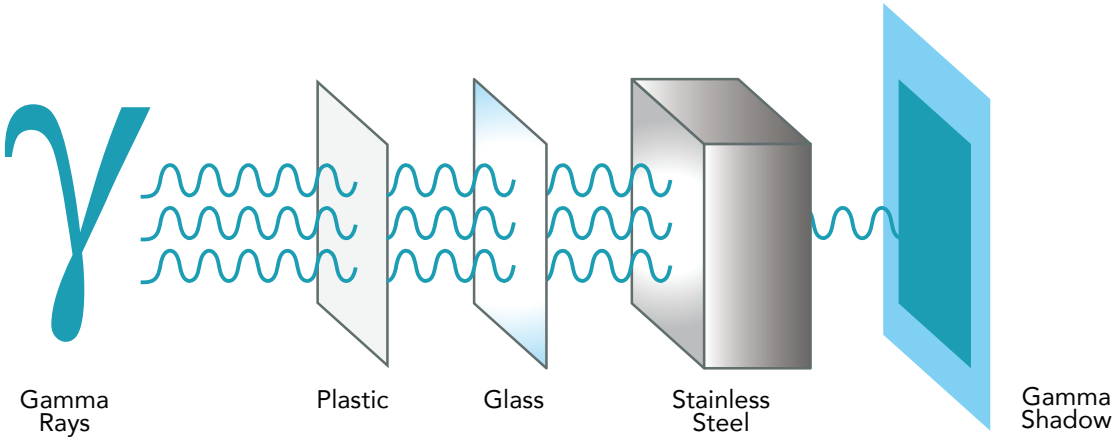
Gamma shadowing occurs when metal objects interfere with the penetration of gamma irradiation during sterilization. Due to their high atomic numbers, certain metals can absorb gamma radiation and create "shadows" behind them where radiation exposure is reduced. As a result, microorganisms may survive sterilization in these "shadow" regions, leading to significant problems for APIs and other sensitive biological materials.

How Does Gamma Shadowing Occur?

Metal Absorption: Metal materials, especially those with high atomic numbers, can absorb gamma radiation meant to sterilize materials.

Shadow Creation: This absorption creates a "shadow" behind the metal object where the radiation is significantly reduced or blocked.

Microbial Survival: Microorganisms can survive within this shadow where radiation is reduced, leading to contamination and potential product failure.



What Risks Does Gamma Shadowing Pose for Bioprocessing?

Bioprocessing setups often contain metal parts, such as valves, fittings and connectors. As such, technicians must understand the risks associated with gamma shadowing.

Risks inherent in using metal parts in single-use bioprocessing applications that rely on gamma sterilization include:

Contamination: Surviving microorganisms may contaminate the system and the end product, leading to product failure, recalls and potential patient harm.

Regulatory Noncompliance: Incomplete sterilization caused by gamma shadowing may lead to nonsterile products that violate regulatory requirements, resulting in fines, penalties and loss of market authorization.

Process Inefficiency: Contamination can disrupt the manufacturing process, leading to increased costs, delays and decreased productivity as organizations seek to correct the problem.

Note: Gamma shadowing is a primary reason that stainless-steel flow meters are often avoided for single-use bioprocessing.

Gamma Shadowing Mitigation Strategies

There are steps one can take to minimize or eliminate the risk of gamma shadowing interference with sterilization. Consider the following tactics:

Careful Material Selection: For any components that may interfere with radiation penetration, choose materials with low atomic numbers, such as plastic or glass, that will not absorb radiation.

Design Optimization: Design components to minimize metal mass, taking care to avoid complex geometries that could create shadows.

By implementing appropriate mitigation strategies, the risks that can result from gamma-shadowing effects can be minimized and the sterility of the bioprocessing setup can be maintained.

ABOUT PSG

PSG® is the global pump, metering and dispensing-solution expert, enabling the safe and efficient transfer of critical and valuable fluids that require optimal performance and reliability in applications where it matters most. Additionally, PSG is a leading provider of flow meters designed to reduce waste and downtime while accurately measuring, monitoring and controlling the distribution of fluids. Headquartered in Oakbrook Terrace, IL, USA, PSG is comprised of several world-class brands, including Abaque®, All-Flo™, Almatec®, Blackmer®, Ebsray®, em-tec®, Griswold®, Hydro™, Malema™, Mouvex®, Neptune®, PSG® Biotech, Quantex™, Quattroflow® and Wilden®. PSG products are manufactured on three continents – North America, Europe and Asia – in state-of-the-art facilities that practice lean manufacturing and are ISO-certified. PSG is part of the Pumps & Process Solutions segment of Dover Corporation. To learn more about PSG, please visit psgdover.com. ***PSG: Where Innovation Flows.***

PSG a DOVER company | PSG BIOTECH

PSG
1815 S. Meyers Road, Suite 400
Oakbrook Terrace, IL 60181, USA
P: +1 (630) 487-2240
F: +1 (630) 487-2250
biotech@psgdover.com
psgdover.com/biotech