Harnessing Electron Beam Capabilities: Aerial's View for the Future of Radiation Sterilization

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Electron beam technology has been utilized as a powerful tool for radiation sterilization for almost six decades [1], offering a compelling combination of safety, speed, scalability, and sustainability. Yet despite these advantages, the technology remains underutilized in many applications where it could deliver significant benefits. Aerial, a French research and technology organization and an IAEA Collaborating Centre based in Illkirch, believes the industry stands at an inflection point. Through a combination of process optimization, advanced simulation techniques, and new release paradigms, electron beam irradiation can be transformed from a niche solution into a mainstream sterilization method for medical devices, single use systems and other irradiation applications.

It is worth noting that electron beam irradiation has been widely used for decades in the processing of polymer materials, cables, heat-shrink tubing, and other industrial products. In these applications, dosimetric considerations, while still important, are less critical since the primary concern is achieving sufficient crosslinking or material modification rather than meeting precise dose specifications. On the other hand, in the field of medical device or single use system sterilization, dosimetry is fundamental. The need to guarantee the sterilization dose throughout the product while respecting maximum dose limits for material compatibility creates a series of challenges that demand rigorous process control, precise dose mapping, and thorough understanding of dose distribution within complex product geometries.

The Case for Electron Beam Technology

Electron beam accelerators are undeniably complex machines, requiring electricity, cooling water, vacuum systems, and for some of them pressurized gases to operate. They demand specialized expertise in electronics, electromechanics, and vacuum technology. However, they become more and more reliable and the benefits they offer are substantial. Electron beam systems are inherently safe, as they can be switched off instantly unlike radioactive sources. They deliver high dose rates, enabling rapid processing. They are scalable and tunable, allowing operators to adjust parameters for different products and applications. Perhaps most importantly in an era of increasing environmental awareness, they are sustainable, relying on electricity rather than radioactive isotopes.

Given these attributes, Aerial poses a fundamental question: why not take greater advantage of what electron beam technology can offer? The answer lies in understanding and overcoming technology's primary limitations.

The Challenge of Dose Uniformity

Unlike gamma radiation from cobalt-60 sources or more recently high energy X rays, which penetrate deeply and are widely used to irradiate pallets of products, electrons have both mass and charge. This means they have finite penetration depth and can create significant dose gradients within irradiated products. Edge effects, scattering, shadowing, and voids within products all influence how dose is distributed, potentially creating unacceptable minimum and maximum dose levels according to the process definition [2].

The Dose Uniformity Ratio, defined as the maximum dose divided by the minimum dose within a product, emerges as the critical parameter in determining whether electron beam processing is suitable for a given application. However, it is essential to understand that there is no universally acceptable DUR value. The only acceptable DUR is one that respects the process definition for a specific product. This determination stems from PQ dose mapping, which establishes Dmin, Dmax, and their variability, combined with product variability, process variability, dose measurement uncertainties, and calibration uncertainty [3].

The process definition establishes two critical boundaries: the minimum dose required for sterilization Dster (or Dpurp for any other irradiation purpose) and the maximum acceptable dose (Dmax,acc) that product materials can tolerate without compromising safety, quality or performance. The acceptable DUR for any product is therefore constrained by the ratio between these two values.
On the lower boundary, the sterilization dose must be assessed precisely rather than defaulting to the traditional 25 kGy benchmark commonly applied in radiation sterilization. While 25 kGy provides a conservative approach with broad applicability, it may be unnecessarily high for many products. Methods described in ISO 13004 and other standards allow manufacturers to establish product-specific sterilization doses based on actual bioburden levels and resistance characteristics. A rigorously determined Dster directly increases the required dose window and consequently the acceptable DUR, making electron beam processing viable for products that would otherwise require the more uniform dose distribution of gamma or high energy X rays irradiation.
On the upper boundary, careful evaluation of radiation tolerance can increase Dmax,acc. [1, 4]
Since this maximum acceptable dose can be radiation technology specific, with materials often tolerating different dose levels depending on whether they receive gamma, electron beam, or X-ray irradiation, a dedicated assessment for electron beam conditions with its significantly higher dose rate, may reveal higher acceptable limits than previously assumed.

By working both boundaries simultaneously, lowering Dster through precise bioburden-based determination and raising Dmax,acc through material-specific radiation tolerance assessment, manufacturers can significantly expand the acceptable DUR range. This dual approach brings more products within reach of electron beam sterilization and its associated benefits of speed, sustainability, and process control and thus, broadens the potential fields of use.

Strategies for Optimizing Dose Uniformity

Aerial advocates for a multi-pronged approach to reducing DUR.
Adapting packaging and product orientation represents a practical intervention. How a product is positioned relative to the electron beam significantly affects dose distribution, and thoughtful arrangement may be appropriate to minimize dose gradients.
Adjusting electron beam energy offers another avenue for optimization. Higher energies, up to 11 MeV or beyond, provide greater penetration depth and can improve dose uniformity for denser or larger products. The choice of energy must be balanced against regulatory constraints and the specific requirements of each application e.g. potential for induced radioactivity in product when energy of electrons exceeds 11 MeV.

Moreover, the use of scattering plates represents a particularly effective approach. [5]
These plates create multidirectional lower-energy scattered electrons that can fill in dose shadows and reduce gradients. Aerial's simulation work demonstrates significant improvements in DUR when scattering plates are employed. The challenge, however, lies in designing and manufacturing scattering plates that can withstand continuous high-energy, high-power electron beam irradiation without being damaged themselves or causing damage to products conveyed underneath.

Material selection, thermal management, and mechanical durability all become critical engineering considerations when implementing this approach in industrial environment.

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The Shift Toward Electronic Dosimetry
Perhaps the most transformative element in the future involves moving from traditional physical dosimetry toward "e-dosimetry," which relies on Monte Carlo simulation and computational modeling. This approach takes inspiration from radiation therapy, where treatment planning is based on detailed patient imaging rather than physical measurements alone.

The workflow Aerial proposes begins with CT scanning of products to create detailed and realistic three-dimensional representations of products. These images can be segmented to identify different materials types and densities within the product, either manually or using machine learning based on the Hounsfield unit values. The segmented model then serves as input for Monte Carlo simulation software such as GATE, Peneloppe, EGS, …, which tracks the behavior of trillions of virtual electrons as they interact with the product materials.

The results are striking in their detail. Amongst many other examples, Aerial's Monte Carlo simulations of a Merk sterility test device box under double side 10 MeV electron beam irradiation produce complete three-dimensional dose maps showing exactly where minimum and maximum doses occur. When compared against physical measurements, the simulated DUR of 1.99 showed excellent agreement with the experimental value of 1.93. This correlation suggests that simulation could reliably predict dose distribution, potentially reducing the need for extensive physical dosimetry during process development. Beyond simply predicting dose distribution, Monte Carlo simulation enables virtual experimentation. Process engineers can test different product orientations, packaging configurations, beam energies, and scattering plate designs without consuming products or beam time. This capability could dramatically accelerate process development while reducing costs.

Release Based on Irradiator Parameters
Aerial's view extends beyond process optimization to encompass fundamental changes in how irradiated products are released. The current paradigm relies heavily on physical dosimetry, with dosimeters placed on a monitoring device to verify that required doses have been delivered. While this approach has served the industry well for over fifty years, it has limitations in terms of information it provides.
The alternative is Release Based on Irradiator Parameters, or RBIP. Importantly, the Irradiation Panel, a group of experts in the field, is actively working on documenting the RBIP method, with an introductory document already published [6].

Under this approach, product release would depend primarily on real-time monitoring of the irradiator's control parameters rather than physical dose measurements. If the machine is qualified (IQ/OQ) and known to be operating within specified parameters, and those parameters have been validated to deliver the required dose, then products processed under those conditions can be released without monitoring physical dosimetry.
This concept, even though already implemented by some service providers, represents a significant departure from current practice and will require substantial development before widespread adoption. One can cite several prerequisites for successful implementation. Industry guidance from bodies such as the Irradiation Panel and AAMI will be essential to establish acceptable regulatory frameworks.

Early adopters must be willing to generate data and build pioneer examples, demonstrating to authorities that RBIP can deliver, at least equivalent or superior assurance of product irradiation. Technical developments are also needed, particularly tools for monitoring irradiator output parameters in real time, including parameters that are currently measured only indirectly.

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Unresolved Questions and the Path Forward
It must be acknowledged forthrightly that the transition to e-dosimetry and RBIP raises numerous questions that the industry has not yet answered. On the imaging side, questions remain about what CT resolution is needed for accurate simulation, how to segment images and assign material properties to different components, and whether reference materials should be established for common product types. Validation requirements are also uncertain, with some products potentially requiring scanning with physical dosimeters to confirm that models accurately predict dose distribution.

The simulation process itself introduces additional uncertainties. Input data accuracy is a concern, encompassing transport, cross-section, energy loss models, energy spectra, beam width, length, and uniformity. Decisions about how far to track particles can affect results. Uncertainty quantification, essential for claiming that simulated and measured values are equivalent, requires further development. Beyond accuracy concerns, the computational burden of radiation transport simulation presents a practical challenge. Calculations can require considerable computational time, particularly for complex geometries and high-resolution models. To make e-dosimetry more appealing for industry adoption, methods to accelerate these calculations are critically important. Aerial is actively working on such optimization strategies to reduce computational overhead while maintaining accuracy. Even fundamental questions about where to measure dose computationally, considering that minimum dose for sterility assurance may be of interest only at product surfaces while maximum dose for material compatibility typically essential in the bulk, need clearer answers.

Perhaps most fundamentally, the industry must agree on how to define minimum and maximum dose in a computational context. Should these values correspond to what a physical dosimeter of a certain size would measure? Should they be based on minimum volume or surface area? Should they represent the 5th and 95th percentiles of the cumulative dose distribution? Different choices will yield different DUR values and potentially different conclusions about process capability.

These questions must be answered in a manner consistent with the industry's successful track record. Radiation sterilization has been used safely and effectively for medical devices and single use systems for over five decades, and new methods must build on this foundation rather than discard it. Updated guidance documents and standards will be needed, potentially including revisions to documents such as ASTM E2232, the Standard Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications.

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Conclusions and perspectives

The future of electron beam irradiation combines pragmatic near-term optimizations with ambitious longer-term transformations. In the near term, manufacturers can reduce DUR and expand electron beam applications through careful attention to process definition, product orientation, beam energy selection, and the use of scattering plates. Monte Carlo simulation, already a mature technology, can support these efforts by enabling virtual process development and providing detailed dose mapping.

Looking further ahead, the industry has the opportunity to reimagine how irradiation processes are qualified and how products are released. Electronic dosimetry based on validated simulations could reduce reliance on physical dosimeters while providing richer information about dose distribution. Release based on irradiator parameters could streamline operations while maintaining product quality.

Realizing this journey will require collaboration across the industry. Standards organizations and groups of experts must develop guidance documents addressing the new methodologies. Regulatory bodies must be engaged to establish pathways for acceptance. Early adopters must be prepared to invest in data production and sharing, as well as in justifying new approaches aimed at obtaining regulatory acceptance. Accelerator manufacturers and integrators must develop the real-time and in-line monitoring tools needed for eliminating risk when implementing RBIP. Thus, R&D and innovation organizations like Aerial must continue advancing science and sharing their findings with the broader community.

The electron beam technology itself is ready. The question is whether the industry is prepared to harness its full capabilities, particularly in the context of radiation sterilization and decontamination applications.

References

[1] Radiation Processing Industry – The early Years, 2025, IIA, https://iiaglobal.com/iia-publications/

[2] ISO11137-1 Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

[3] ISO/TS 11137-4, Sterilization of health care products – Radiation – Part 4: Guidance on process control

[4] Guide to establishing the maximum acceptable dose under ISO 11137 Part 1. The Irradiation Panel, 2025, https://www.irradiationpanel.org/publications/

[5] Dosimetry techniques for electron beam radiation processing, PhD F. KUNTZ

[6] Release from an Electron Beam Irradiation Process Based on Irradiator Parameters (RBIP): Introductory Guidance. The Irradiation Panel, 2025, https://www.irradiationpanel.org/publications/

[7] ASTM E2232-21 Standard Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications, 2021, ASTM

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