PROCESS CHAIN AND LOGISTICS

RADIATION STERILIZATION AND RADIATION CROSSLINKING AS AN OUTSOURCED PROCESS

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CONTENTS

1. INTRODUCTION

In different industries, products undergo an outsourced process step prior to their further processing or final delivery: They are treated in special plants with ionising radiation. Depending on the area of application, high-energy beta and gamma rays provide a targeted and precisely dosed upgrading of product properties, or convert products into a sterile state. The great advantage of a treatment with ionising rays is that the products can be used or further processed immediately after a simple approval step (dosimetric release) – without further tests or storage and waiting time.

→ **Sterility through radiation sterilization**
Radiation sterilization with high-energy radiation destroys pathogenic germs, mould and spores in materials and objects quickly and it is environmentally friendly. Its use is crucial for industries in which sterilization is indispensable, such as medicine technology, biotechnology or the pharmaceutical sector. Since: Even with the highest possible hygienic care and controlled production processes in clean rooms, it is not possible to manufacture a completely sterile product – a subsequent sterilization process is always necessary. In many other industries, sterility is a prerequisite for a reproducible and qualitatively high-class production result, for example, when it comes to producing packaging material and processing aids for the cosmetic, pharmaceutical or food industry.

→ **Upgrading for plastics through radiation crosslinking**
Radiation crosslinking, in turn, is a refining step to achieve high-performance plastics. Radiation triggers permanent crosslinking in the material, which changes the physical properties. The products become more resistant, for example, against wear and tear, high temperatures or chemical influences. This method is ideally used to optimise moulded parts out of commodity plastics, such as cable, pipe or tubing products.

More expensive high-performance plastics can thus be replaced in many applications without compromising the quality.

Apart from a few exceptions, many of the irradiated products are parts of a series production subject to specified scheduling in the logistics chain. In the medical technology industry, countless sterile products have to be delivered every day, from wound coverings over cannulas to implants and diagnostics components. The same applies for users of radiation crosslinking. In the automotive industry, for example, the most varied supply chains are meticulously coordinated with one another in part. For manufacturers and suppliers, these general conditions mean that the irradiation production step has to follow after production smoothly and expeditiously.

2. IRRADIATION AS OUTSOURCED PART OF THE PRODUCTION PROCESS

Irradiation of products with beta and gamma rays is generally carried out by specialized service providers, since the operation and setup of such plants is complex. In this context, operators of gamma plants and electron accelerators have to meet extremely high structural safety standards and be equipped with extensive monitoring technology.

External providers of irradiation services have an infrastructure with routine processes which guarantee smooth integration ranging from an individual order up to series production.

External service providers have a clear advantage particularly when it comes to series production. Their processes are highly automated due to capacity utilisation and expertise, and ensure the necessary speed and high quality standard in the processing. This comprehensive know-how has been built up elaborately over a longer period and is a further reason why it is rarely cost-efficient for manufacturers to operate their own irradiation facilities in practice.

3. HOW ARE THE PROCESSES DEFINED?

The basic scheme of an irradiation service is actually very simple. Products are delivered, irradiated and collected again, externally unchanged. In fact, however, complex planning takes place behind the scenes and is an essential pillar of the core competence of the service provider. The first step into a cooperation begins with a comprehensive consultation and verification of the technical feasibility. It is therefore important to contact the service provider at an early stage.

What many customers don’t know: The advisory competence already includes the selection of material and the design and

continues up to the packaging scheme. Cooperation should thus ideally begin in the development of the product.

Both beta and gamma rays are suited for the sterilization and crosslinking of products. The technical differences of both types of radiation are shown in the following table:

Table 1: Technological differences

Parameter	Electron radiation	Gamma rays
Dose rate	high	low
Depth of penetration	medium	very high
Irradiation time	a few seconds	several hours
Radiation source	Electric current	Cobalt-60
Irradiation unit	Single cartons, individual pieces, bulk goods, wrapped goods	Pallets
Description of procedure	Electrons are emitted from a hot cathode and then accelerated to a very high velocity in a high vacuum by means of a strong electric field. Upon leaving the accelerator, the electron beam is deflected by a magnetic field onto the product in lines at a high frequency.	Gamma rays are created through the decay of a radioactive isotope, e.g. Cobalt-60. The rays have a high penetration depth and penetrate entire pallets or lots. Individual sources of Cobalt-60 are arranged and integrated into the source rack, by which means a unique radiation field is generated. The products to be sterilized are transported through this radiation field via a fixed pre-specified path. In the process, the necessary radiation dose is emitted into the product.

In the case of beta radiation, energy-rich electron rays only have to be applied for a few seconds. Due to the limited penetration depth of the rays, the goods are usually irradiated in smaller transport packaging units such as cartons, as bulk goods or as continuous products. Under optimal conditions, whole truckloads can be sterilized within a few hours. By contrast, irradiation with gamma rays takes several hours. Radiation is created through the decay of a radioactive isotope and clearly shows higher degrees of penetration depth than the beta rays. As a rule, the products therefore remain directly on the transport pallets and are conducted through the facility on these.

When deciding on which process, the objective of the irradiation naturally plays a key role. As shown in the following sections, this is not the only factor.

4. RADIATION STERILIZATION PROCESS

Radiation causes damage of the DNA in the nucleus of microorganisms. They die and reliably lose their ability to reproduce.

With the help of test series in the run-up to irradiation treatment, experts determine whether the bioburden was reduced in compliance with the regulations. Factors such as the radiation dose and packaging scheme also play a decisive role in this context.
Trial runs with dosimeters at definite positions in the cartons register the applied dose and are evaluated in conjunction with all further tests. On this basis, the customer and service provider develop an appropriate packaging scheme. In the series process later on, details such as packaging density, packing material, size of cartons, product alignment and product structure and composition are of major importance for efficient irradiation. In close coordination, the packaging is planned from the outset, enabling the irradiation phase to be carried out efficiently. Once defined, the result is completely reproducible.

Since the properties of polymer materials may change through irradiation, the service provider also assesses their behaviour. Both the product as well as the primary packaging of medical devices have to maintain defined properties over the specified expiry date. Sealing seams, for example, and the integrity of the system are tested. All the tests involved in this process are described via the packaging validation. Since repackaging can be used again, it is also part of the process definition.

5. RADIATION CROSSLINKING PROCESS

When plastics are refined through irradiation, many production processes are simplified through the omission of costly post processing or directly through simpler processing procedures. An example of this, amongst others, is the replacement of metals through high-performance plastics in the area of lightweight construction. Nevertheless, these high-performance plastics with corresponding material properties are expensive and often more difficult to process. With radiation crosslinking, it is possible to bring less costly materials and those that are easier to process to an equivalent level.

When crosslinking components, for example, the original processing procedures are maintained and do not have to be altered.

Only the end product is treated - the production does not have to be adjusted. Radiation crosslinking is the last step after moulding and can be integrated in the production chain during transport to the end user. Since polymer materials react differently to irradiation, the specialists advise on the selection of material and help to define the best material for the intended purpose. In this case, too, test series and the testing of materials play an important role in defining the process.

In the application development, the optimal arrangement and radiation dose are determined in advance.

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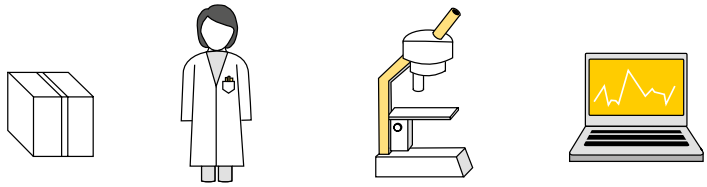


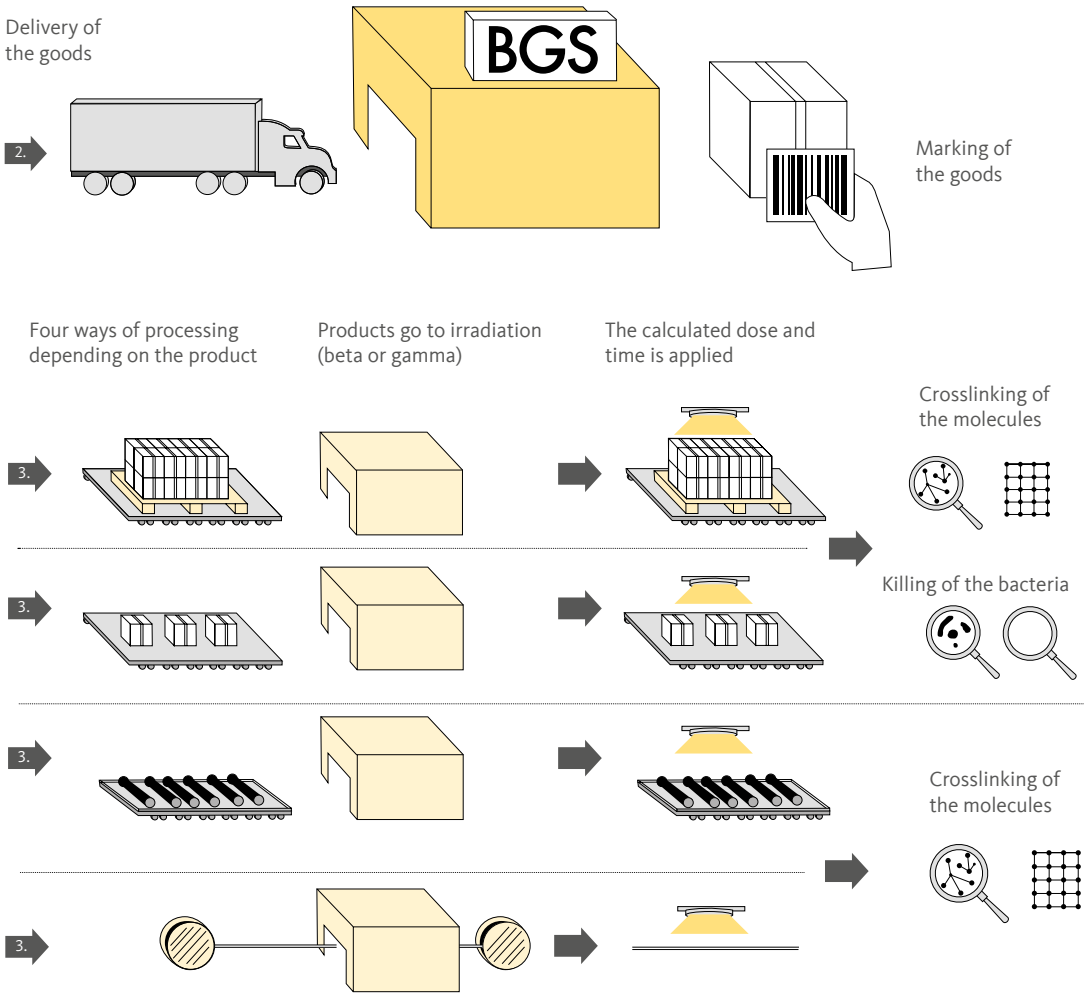
Input into the ERP system

6. FROM DELIVERY TO COLLECTION: HOW DOES THE IMPLEMENTATION WORK IN PRACTICE?

The objective of cooperation is always to establish a highly automated and smoothly integrated process for each product. This allows large volumes to be processed within a short time. On the one hand, the basics for this are attributable to seamless coordination with the customer and previous consultation; on the other hand, they are due to the process technology of the service provider on site. This ensures that the desired treatment result is achieved under all circumstances. The processes are secured and reproducible since most products that undergo irradiation treatment are highly sensitive. Sterility does not tolerate deviations and errors, no more than do cable harnesses used in the automotive industry. Not least of all, it is about seamless linking of all information and complete documentation of all processes carried out, since the irradiation phase is part of a validated process chain with corresponding requirements.

The entire process at BGS Beta-Gamma-Service is an example of the practical implementation of the vision “Industry 4.0”: Although data control and communication make irradiation a processing step that takes place outside of the customer’s premises, it is seamlessly integrated in the customer’s work flow. To ensure complete traceability, each order is recorded and the regulatory requirements documented from the time the goods are received over the irradiation process up to delivery or collection. This starts when the goods are delivered. In the incoming goods area at BGS, a software-controlled system is used to label the products with a barcode. In this way, the route of each packaging unit can be controlled and traced in the facilities, regardless of the irradiation process the product undergoes.

The system thus documents the important parameters of the process such as the radiation dose which is to be applied. In order to ensure rapid throughput of the order, BGS should have an order placement prior to arrival of the goods.



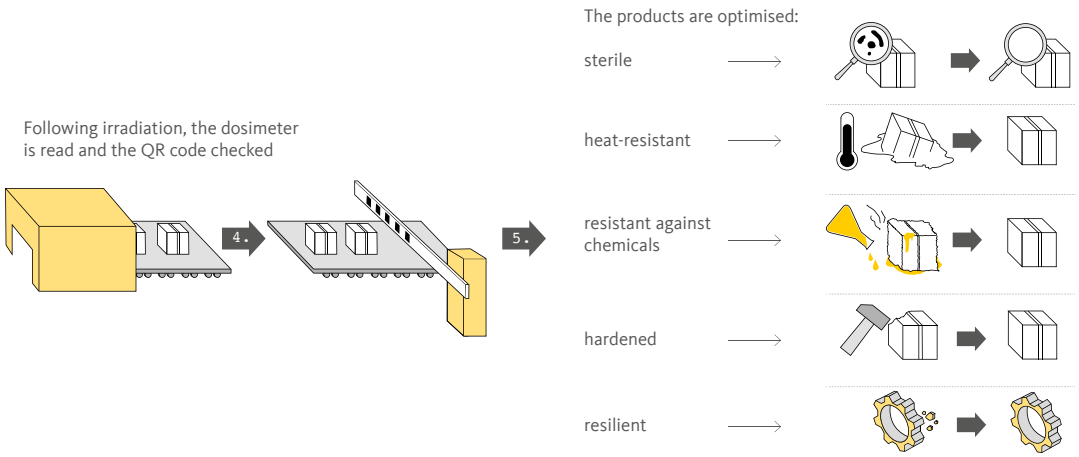
Depending on the type of product, the goods undergo one of four possible process variants during irradiation. If the products are treated with gamma rays, they remain on the transport pallets due to the high degree of penetration depth. The fully automated conveyer system at BGS is aligned with industry and Euro pallets. The plant control system ensures that each pallet completes the prescribed number of cycles in the system. In this way, the radiation dose is reproducible and is complied with upon each delivery of goods. The plant is set up in such a way that different products with differing radiation doses can be treated simultaneously.

In the case of radiation with beta rays, the processed packaging units are smaller due to the lower degree of penetration depth. The cycle through the radiation unit in the facility itself only takes a few seconds. Individual cartons or cassettes on conveyor belts are conducted through the facility. The delivered goods are depalletised accordingly and after treatment, they are repacked in their original state in compliance with the packing lists. Withdrawal from the repackaged goods does not take place. Loose bulk goods or components such as tube bundles and poles measuring up to 12 metres in length and 1.6 metres in width are conveyed through the facility on cassettes. Continuous goods such as cables, pipes and tubes are conducted through the irradiation process in a wrapping process.

7. WHAT HAPPENS AFTER IRRADIATION?

After radiation sterilization has taken place, the radiation dose applied is controlled with the help of a dosimeter attached to the product. If everything is in compliance with the specifications, quality assurance grants immediate approval and the product is then ready for immediate use without waiting times. In contrast to sterilization with rays, EO sterilization requires waiting times for degassing and approval tests. To the extent materials are suited, irradiation with beta and gamma rays is the best choice for time-demanding supply chains. The transport logistics to the end customer follows seamlessly. This results in huge advantages in terms of time and processing at reduced costs.

In the case of radiation crosslinking, additional material tests are necessary as a rule. These are dependent on the areas of application.



The irradiated products are not dangerous. They themselves do not radiate and can thus be further processed and used immediately.

The usual lead time at BGS is between 5 and a maximum of 10 working days. Depending on the volume of delivered goods and utilisation, BGS will state a probable pick-up date in each case. Following each irradiation, the customer automatically receives an email from the system with the definitive order for collection, irrespectively of the time of day. This way, the customer can immediately arrange the further logistics and organise the collection of its goods. Documentation and certificates are part of each irradiation treatment, which are concurrently available for the customer together with the completion note. The forwarding agent must present the completion note when collecting the goods.

Express treatments at special conditions are possible within 24 hours depending on utilisation and the order size. Automation-capable packaging / drums are decisive for the processing costs.

8. WHAT SHOULD CUSTOMERS AND FORWARDING AGENTS BEAR IN MIND WITH REGARD TO DELIVERY AND PACKAGING?

For loading and unloading of the trucks, BGS has standard ramps at all locations which should be used with priority. Depending on the location, the forwarding agent can load and unload special goods sideways or make use of a loading crane. It is important to discuss deviating deliveries and collections during the preliminary stages, so that they can be integrated smoothly into the logistics process.

Packaging materials that can be recycled such as wood, paper, cardboard, or plastic lose their firmness and change their properties if they are irradiated repeatedly. If deliveries are made frequently, it is recommended to replace the packaging and pallets regularly. The experts will be happy to offer advice about how often it makes sense to exchange the respective packaging. If the packaging is used frequently, care must be taken that the irradiation labels and indicator points on the packaging are completely removed after each treatment to avoid any mix-ups.

- → **Industry pallet:** 120 x 100 cm, height up to 190 cm, weight up to max. 750 kg
- → **Euro pallet:** 120 x 80 cm, height up to 190 cm, weight up to max. 750 kg
- → **Packed on pallets:** Among other things, cartons, sacks, barrels, big bags, racks
- → **Bulk goods** in containers and mesh pallet cages

The pallets have to be suitably stable for automated processing. In the case of special pallets, it has to be verified in advance whether the format can be transported by the system at the location. The pallets will not be exchanged during the process and remain in possession of the customer. This makes the processing steps easier since forwarding agents do not have to provide substitute pallets, but can pick up the goods in the same packaging scheme as they delivered.

9. AT WHICH LOCATIONS ARE THE SERVICES OF BGS AVAILABLE?

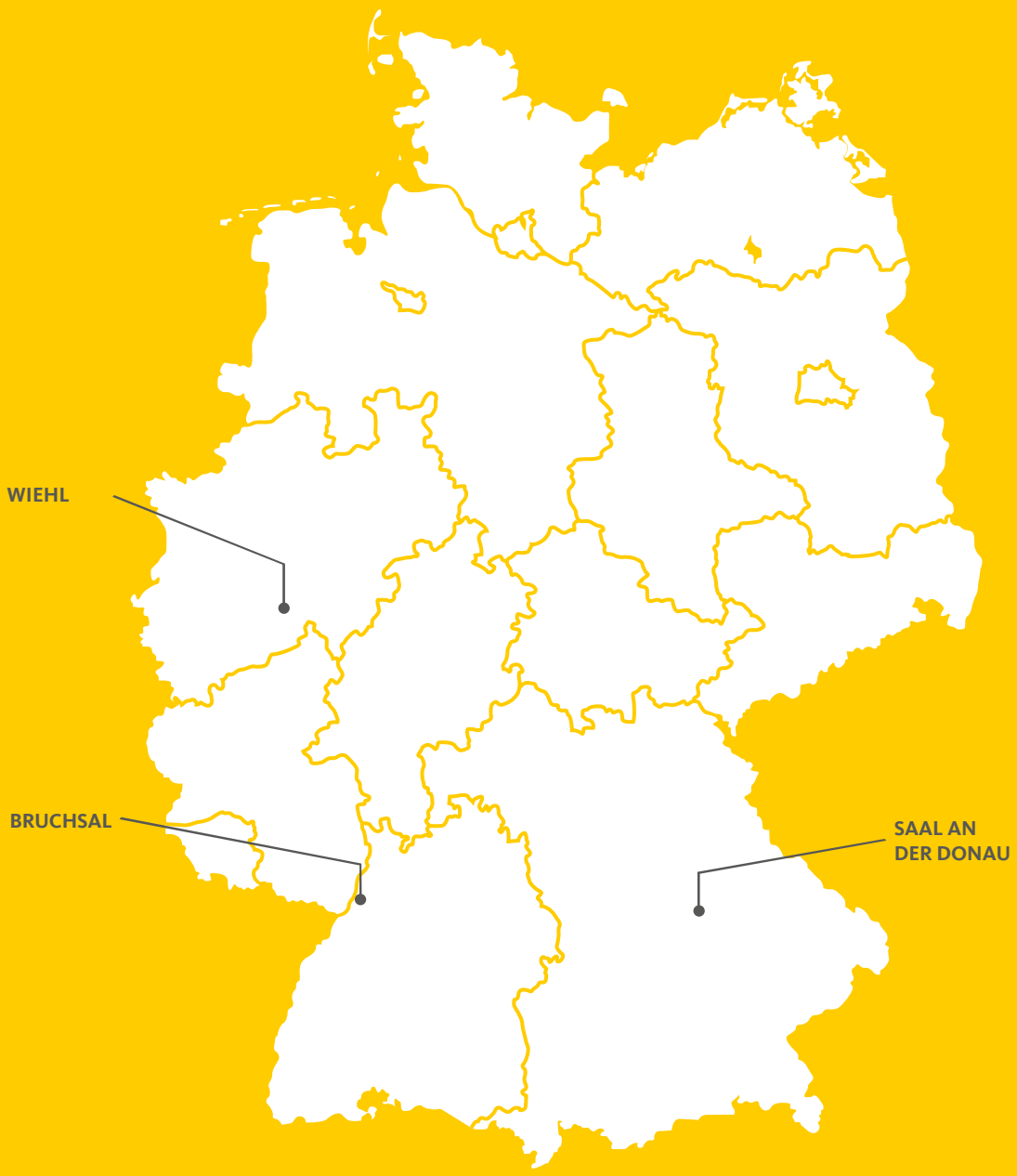
Irradiation will take place at the location determined in consultation with the customer. In addition to the transport routes, the type of product handling, plant-specific aspects and capacity utilisation of the facilities play a role. All plants meet the latest state of the art and are differently configured. In this way, a large range of products can be treated and a disruption of the facilities compensated. Nevertheless, the “principle of redundancy” applies: Each location is able to take over the products of the other locations. If unforeseen disruptions or machine failures occur or express requests are accepted, these can usually be absorbed by one of the other locations. BGS thus makes an essential contribution to meeting its delivery commitments dependably and guaranteeing planning reliability.

Business hours for delivery / collection of the goods at all locations: Mon. – Fri. 7.00 a.m. to 5.00 p.m. or by appointment

→ **Wiehl (North Rhine-Westphalia)**
The location in Wiehl has four electron accelerators with an energy field of 0.5 to 3.0 MeV and max. 150 kW. The facilities are equipped with flexible handling systems for continuous products such as cables, pipes and tubes as well as for the irradiation of piece goods such as cardboard packages and components.In addition, Wiehl operates a 5 MCi Cobalt-60 gamma facility, where Euro and industrial pallets up to a height of 190 cm can be irradiated.

→ **Bruchsal (Baden-Württemberg)**
Bruchsal has two electron accelerators with an energy field of 2.5 to 10.0 MeV. Both facilities are equipped with flexible handling systems for continuous products such as cables, pipes and tubes, as well as for the irradiation of piece goods such as cardboard packages and components. Since 2018, BGS has been operating a new ultramodern 6 MCi Cobalt-60 gamma facility in Bruchsal, where Euro and industrial pallets up to a height of 190 cm can be irradiated. In addition, it is also possible to irradiate components at this location up to a length of 12 metres x 1.6 metres in width such as tube bundles, poles and large components.

→ **Saal a.d. Donau (Bavaria)**
In Saal, a 10 MeV electron accelerator with a fully automated conveying system for packing and unloading of Euro pallets enables the radiation of large quantities with short turnaround times. In addition, a 5 MeV electron accelerator with variable acceleration voltage is available for the irradiation of continuous products such as pipes, tubes, profiles, and cables.



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