BBF Sterilisationsservice GmbH * Willy-Rüsch-Straße 10/1 * 71394 Kernen

To our customers

[Unsere Zeichen/Unsere Nachricht vom]	Telefon	Fax	Datum
Site Modernization Circular Letter January 2020 E; NL/-	07151 94570-80	07151 94570-12	27.01.2020

Modernization of the radiation system and the dosimetry system

Dear Customers,

Two years ago we informed you about the planned modernization of our irradiation site.

In the meantime, the extensive planning work has been completed and we have received nuclear approval for the planned measures.

Thereby the prerequisites for the implementation of the measures have now been reached and our partner, Framatome GmbH, has been commissioned with the realization.

Due to the complexity of the project, we are currently unable to present a specific schedule for the further course of the work. However, we are working on creating this in the next few weeks.

First, the system and the control system must now be built and programmed. After approval of the Factory Acceptance Test, the system will then be set up at BBF and initially subjected to a test operation / simulation.

Only then will the final installation and commissioning take place in the hot cell. Together with the necessary qualification measures, we currently expect a downtime of approx. 4 weeks.

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When creating the schedule for the further course of the project, we will plan for a lead time of approx. 12 months and will inform you in due time. During this lead time, we will expand our irradiation capacity through organizational measures and additional work shifts. Thus we would like to put you in a position to build up a sufficient inventory by expanding your production in order to be able to bridge the downtime.

We would also like to point out that we have commissioned DEKRA as our certification body to carry out an audit of the modernized irradiation system, including the associated qualification documentation.

As already stated in our letter dated January 22, 2018, we still assume that the effects of modernizing the plant on the established dose windows are neglectable. However, we will only be certain about this as a result of the qualification measurements (OQ) to be carried out.

The basis will furthermore be the standard cycle with a dose window of 25 to 45 kGy. In case of deviating dose windows in particular, there may be a higher risk that a new product-specific validation (dose distribution measurement) and, as a result, an increase in the maximum acceptable irradiation dose may become necessary.

We would also like to point out that we will start introducing a new dosimetry system in the next few months, probably in the second quarter of 2020. The proposed alanine dosimeters offer a number of advantages over the Red Perspex dosimeters, e.g. an even higher measuring accuracy.

After a certain (not yet defined) transition period, we will probably be able to offer Red Perspex dosimeters in special cases only.

We are also in the process of implementing a new process software for our radiation service. In this context, we will analyze the existing product-specific radiation processes. We will contact you in the coming weeks and months to clarify the necessary details and to coordinate the specifications with you.

Without an adequate process specification, which must be explicitly named in your order in the future, we will no longer be able to carry out your irradiation orders.

Finally, we would like to point out that we are currently planning to reload cobalt in May 2020 - not least to ensure the necessary irradiation capacity that we need to

build up your inventory. We will inform you in due time about the time of the one-week system shutdown.

We will keep you up to date on the progress of the addressed projects and the plant modernization on our homepage, especially about duration and dates of plant downtimes.

We hope that this will provide sufficient planning security for you and thank you by now for your understanding and support in the work ahead and any restrictions and changes that may be associated with it for you. We are also happy to provide you with detailed information personally.

Kind regards

Dipl. Ing (FH) Johannes Jandl
Head of Gamma Irradiation Services

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Head of Business Development