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To our customers

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Site Modernization Circular Letter July 2020E; /-	(07151) 94570-0	(07151) 94570-12	21.07.2020

## Modernization of the radiation system and the dosimetry system

Dear Customers,

At the beginning of this year we informed you about the planned modernization of our irradiation site.

Our scheduling is now more specific and we would like to inform you that installation and commissioning of the hot cell will now take place in August 2021. Together with the necessary qualification measures, we currently expect a downtime of approx. 4-6 weeks.

As already mentioned in our last information letter, we will expand the radiation capacities in advance with organizational measures and additional work shifts. By doing this 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.

According to our calculations, we assume that the effects of the plant modernization on the established dose windows are insignificant. However, we will only be certain of this as a result of the qualification measurements (OQ) to be carried out.

The basis will continue to be the standard cycle with a minimum dose of 25 kGy.

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We also informed you about the introduction of new process software and the alanine dosimetry system, as well as the need to analyze the existing radiation processes and to develop sufficient process specifications.

In this situation, the new ISO / TS 11137-4: 2020-06 has now appeared, which addresses the process control of radiation processes.

Against this background, we assume that the existing radiation processes must be checked not only with regard to the process specifications for the new software, but also with regard to the instructions of the new standard. The question also arises whether new dose distribution measurements and new process specifications derived from them may be necessary.

Due to the brand new ISO / TS 11137-4 it cannot be estimated at present whether validations have to be repeated or not. Of course, we will be happy to provide you with further information if you have any questions regarding the validation status of your products.

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

On our homepage we will continue to keep you up to date on the further progress of the plant modernization, especially of course about the duration and dates of the plant downtimes.

Kind regards

**Dr. Norman Layh**

Head of Business Development