HEALTHCARE WASTE INSTITUTE
NATIONAL WASTE & RECYCLING ASSOCIATION

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Submitted electronically via https://www.regulations.gov/

Ms. Keisha Thomas
Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA– 2021–N–0507
Medical Devices; Quality System Regulation Amendments

Dear Ms. Thomas:

The Healthcare Waste Institute (HWI) of the National Waste & Recycling Association (NWRA) is pleased to submit comments on the proposed rule, *Medical Devices; Quality System Regulation Amendments*, Docket No. FDA–2021–N–0507. The HWI represents manufacturers and service providers as well as other professionals in the healthcare waste management industry. The HWI is an advocacy organization within NWRA, a not-for-profit trade group serving the interests of the solid and healthcare waste industries. The HWI supports private companies across the United States that manage healthcare waste, including regulated medical waste, waste containing potentially infectious substances and pharmaceutical waste, through collection, transportation, treatment and end disposal.

HWI agrees with FDA that it will be beneficial to harmonize the current quality management system requirements with those used by other regulatory authorities (i.e., ISO 13485). As such, we generally support the proposed rule. However, we have some specific comments below for proposed changes.

Amend effective date

FDA proposes that the final rule would become effective one year after publication. For small, domestic companies that do not export their products, it will take longer than one year to come into compliance with the new standards

as they are not familiar with the ISO 13485 standards. In order to allow adequate time for changes to be made, HWI recommends that the final rule should become effective 2 years after publication.

Reconsider sharps disposal container regulation

Generally, sharps disposal containers are regulated by the FDA as class II devices subject to premarket notification (510(k)). As such, we understand that they are subject to Part 820. However, there are no regulatory standards for sharps disposal containers in the current federal Food, Drug, and Cosmetic Act (FDCA). Instead, FDA references standards established by the federal Occupational Safety and Health Administration (OSHA). Nor are sharps container standards included in ISO 13485. In fact, the European Union does not consider sharp disposal containers to be medical devices (Regulation EU 2017/745).[1] Given that, we suggest removing any requirements that would subject sharps disposal containers to the amended Part 820 regulations.

If FDA decides to maintain sharps disposal containers as medical devices, we recommend that FDA reclassify them from Class II to Class I, given their relatively low risk of transmitting infection.

HWI appreciates your consideration of our comments. Should you have any questions, please call Anne Germain at 202-364-3724 or e-mail at agermain@wasterecycling.org.

Very truly yours,

Darrel K. Smith
President & CEO

[1] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG