Federal Acquisition Regulation:
Minimizing the Risk of Climate Change in Federal Acquisitions:
Suggestions from the Association of Medical Device Reprocessors

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Submitted to the Federal Register Docket: FAR-2021-0016-0001 14 December 2021

The Association of Medical Device Reprocessors (AMDR) is the global trade association representing the interests of regulated, commercial medical device reprocessing companies. We respectfully submit these comments in response to the above-referenced docket. We focus our comments on the Department of Defense (DoD) and its procurement of healthcare products. Over 80 percent of US Healthcare emissions come from scope 3, or the supply chain. Given disruptions to supply chains for healthcare products, we believe circular solutions such as medical device reprocessing offer DoD a way to build supply chain stability and reduce both emissions and costs. We provide brief answers to requests A through C based on our experience.

We also attach a background document (*The Reprocessing Solution: Reducing Greenhouse Gas Emissions and Lowering Healthcare Costs*) that offers foundational information about the existing, regulated use of reprocessed "single-use" devices (SUDs) in over 10,000 hospitals in the US, Canada, in a number of EU countries, the UK, and Japan.

A recently peer reviewed, published Life Cycle Assessment (LCA) examined 15 major environmental impacts comparing the creation of virgin, or original electrophysiology catheters, used in certain cardiovascular surgeries, to that of their FDA-regulated reprocessed alternatives. In 12 of 15 environmental impacts, the reprocessed device was found to be superior. We review the analysis further in our responses below but wish for it to serve as an example for the type of complete analysis required to make the best purchasing decision now also contemplating sustainability considerations.

We hope DoD will, as the Federal Register notes, "lead by example" to ensure "that the Federal Government manages climate-related financial risk within its own procurement activity." Medical device reprocessing is a proven, regulated means to build a more resilient and less environmentally damaging healthcare supply chain. DoD acute care facilities are already reprocessing with AMDR members, but at a fraction of their potential. We hope DoD will lead by example to prioritize sustainable procurement solutions such as medical device reprocessing.

(a) How can greenhouse gas emissions, including the social cost of greenhouse gases, best be qualitatively and quantitatively considered in Federal procurement decisions, both domestic and overseas? How might this vary across different sectors?

Greenhouse gas emissions must be considered in Federal procurement decisions if we hope to address climate change and meet the Administration's noble emission targets. In the health sector, we suggest looking abroad to the UK for approaches to quantifying and qualifying reductions in greenhouse gas emissions including well-designed Life Cycle Assessments.

One solution identified through the UK's examination: the United Kingdom's National Health Service (NHS) advocates for the use of reprocessed (referred to as "remanufactured" in the UK and Europe) devices as part of its Net Zero commitment. An interview with Alan Wain, Chief Operating Officer for Supply Chain illustrates the decision. UK's National Health System UK offers a look into the Scope 3 commitments we would like to see from the DoD. NHS Remanufacturing Guidelines are attached.

As DoD runs military hospitals, and as over 80% of greenhouse gas emissions come from Scope 3, or supply chain sources, we think this to be an important example.[1] The research sourced here from Eckleman, et.al, provides an excellent argument for considering the health sector among the first areas in which addressing climate change is of paramount importance.

Within government-funded health facilities, we see a need for strong Administration level guidance. For example, our members report to us that while most military hospitals reap the greenhouse gas emission and cost reduction benefits of reprocessing, the entire Veterans Health Administration's (VHAs) hospital system does not. The VHA is the largest hospital system in the country, yet it refuses to use any reprocessed devices despite over 20 years of FDA-regulated use with no evidence of increased risk to patient safety. The VHA are spiking their greenhouse gas emissions (and increasing procedure costs unnecessarily). AMDR notes that the VHA is the only health system in the country NOT availing itself of FDA regulated, reprocessed devices. DoD collaboration with VHA on this subject could make an immediate reduction in US health facilitation emissions generation, streamline and strengthen supply chains and reduce costs.

(b) What are usable and respected methodologies for measuring the greenhouse gases emissions over the lifecycle of the products procured or leased, or of the services performed?

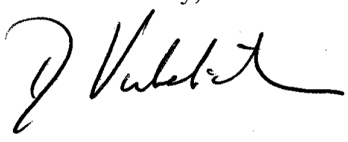
We encourage review of the outstanding Life Cycle Assessment conducted by Germany's prestigious Fraunhofer Institute. The peer reviewed, published LCA examined 15 major environmental impacts comparing the creation of virgin, or original electrophysiology catheters, used in certain cardiovascular surgeries, to that of their FDA-regulated reprocessed alternatives. In 12 of 15 environmental impacts, the reprocessed device was found to be superior. We review the analysis further in our responses below, but wish for it to serve as an example for the type of analysis required to make the best purchasing decision possible for healthcare products given sustainability considerations. We hope future studies will also take cost into account. Reprocessed devices for example are not only environmentally superior in climate change-related categories, but also cost 30 to 40% less than original devices.

(c) How can procurement and program officials of major Federal agency procurements better incorporate and mitigate climate-related financial risk? How else might the Federal Government consider and minimize climate-related financial risks through procurement decisions, both domestic and overseas?

We hope that DoD and other agencies do not assume that environmentally superior products necessarily cost more. In fact, reprocessed or reused products are typically less expensive than their original counterparts. According to internal AMDR data, hospitals that used reprocessed "single-use" devices saved over $442 million in 2020 simply by using reprocessed devices instead of original devices. We note however that overall savings could be much more. If every hospital saved as much as the top 20% of those who reprocess, U.S. hospitals would save over $2.6 billion, according to our internal analysis.

We believe the highest priority in purchasing more environmentally sustainable products should be given to products that are found to simultaneously lower greenhouse gas emissions *and* cost less. If LCAs indicate that reused (or reprocessed, in our case) product is superior in both measures, such products should be given priority status.

Thank you and sincerely,



[1] Eckelman MJ, Haung K, et. Al., Healthcare Pollution and Public Health Damage in the United States: An Update. **Health Affairs** 39:12. 2071-2079 (2020).

Daniel J. Vukelich, Esq., CAE
President
Association of Medical Device Reprocessors
2000 Pennsylvania Ave. NW, Suite 3000
Washington, DC 20006
202.489.7867
Dvukelich@amdr.org
WWW.AMDR.ORG

See attached: NHS Guidelines on Remanufacturing.