Instrumentation Laboratory
A Werfen Company

This document serves as the Non-confidential version of IL Responses to the EU Commission.

1. The application, received by the Commission in July 2017, specifies that IL expects the sensor cards to be RoHS compliant within 7 years (i.e. in July 2024). Please specify until when the exemption shall be needed, i.e. the expiration date that you apply for in the case of this exemption.

   Answer from Instrumentation Laboratory: As noted in our application sent to the EU Commission services on 16th June, cf. Commission confirmation of receipt of 16th June, we expect that RoHS compliance will be achieved within 7 years. As the current exemption expires on 31st December 2018 we propose that the exemption is needed until 31st December 2025.

   The selection of a resin candidate was planned to occur by 23rd June 2017 according to the Revised Project Plan provided in Table 3 of the application received on 16th June. We've tested substantial resin candidates that have demonstrated limitations in performance for our GEM products; therefore, none have been suitable to replace the existing resin formulation.

   We are continuing to refine our criteria to better identify potential RoHS compliant alternatives based on the insights gained from our testing and research. In appreciation of the challenging nature to change the GEM sensor card resin in fine balance with the other card components to preserve the optimal system performance today, the prior timeline no longer reflects the appropriate effort or durations. Our belief is that we can achieve a RoHS compliant GEM sensor card, and therefore; RoHS compliant products by 31st December 2025 if permitted to do so.

2. Information is provided as to the amount of lead to be placed on the EU market through this exemption. The information is understood to relate to PVC sensor cards placed on the EU market solely by IL. Please estimate how much lead is placed on the market through the use of this exemption by all manufacturers of equipment using such PVC sensor cards.

   Please specify assumptions and calculations so that the basis for this estimation is clear.

   Answer from Instrumentation Laboratory: PVC based sensors are common to Ion selective electrodes used in blood gas analyzers, clinical chemistry analyzers and other water quality analyzers. The specific formulations of the PVC used and sensor designs used by each manufacturer is generally proprietary information that is not public domain information for Instrumentation Laboratory and for that reason it is not feasible for us to provide the actual amount of lead placed on the EU market. This is based on our estimates.

	Lead weight estimated for IL blood gas analyzers (kg)	**Lead weight estimated for all blood gas analyzer manufacturers (kg)**
TOTAL	48.14	144.43

1 Lead/year calculation

3. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated.
   For this purpose, please provide details in respect of the following in relation to all EEE placed on the EU market through this exemption (i.e., not just by IL):
   a. Please estimate the related volume of EEE concerned and the respective amount of lead to be avoided should the exemption not be granted.

      Answer from Instrumentation Laboratory: Please see the response to question 2 above for the respective amount of lead in the sensor card. The EEE estimate provided here is based solely on the sensor card.

	EEE estimated for IL blood gas analyzers		EEE estimated for all blood gas analyzer manufacturers	
	(kg)	(m^3)	(kg)	(m^3)
TOTAL	963	0.74	2,889.00	2.22

2 EEE/year calculation based on the sensor card weights

b. Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted. In this respect, please clarify if such a scenario would result in limitations to further use and maintenance of certain equipment (e.g. equipment placed on the market in the past, refurbished equipment, etc.).

Answer from Instrumentation Laboratory: The EEE volume provided here is calculated from the dimensions of the GEM analyzers. With our analyzers, similar to other analyzers on the market, the analyzer cannot be operated without the cartridge that contains the GEM sensor card. This estimate is based on an assumption that other manufacturers' systems have similar dimensions as the GEM analyzers by IL. The estimated amount of lead calculated here is very small compared to the amount of EEE estimated to become part of the waste stream due to the analyzers becoming inoperable/nonfunctional should the exemption not be granted. Another waste consideration is that of EU physician resources by not having the analyses provided by these devices to effectively treat and manage disease and conditions in an efficient turnaround time with minimal return visits. Also, please, consider that patients could have much longer hospital stays than is necessary for their ailments, thereby preventing institutions from being effective at treating as many patients as possible.

	Analyzer-based EEE estimated for IL blood gas analyzers		Analyzer-based EEE estimated for all blood gas analyzer manufacturers	
	(kg)	(m^3)	(kg)	(m^3)
TOTAL	111,640.37	316.84	334,921.11	950.52

3 EEE/year calculation

c. Please estimate possible impacts on employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors in which possible impacts are expected – for example PVC sensor card manufacturers and manufacturers of in-vitro diagnostic medical devices for the analysis of blood, supply chain, retail, etc.

Answer from Instrumentation Laboratory: 90% of the blood gas analyzer offerings no longer being acceptable for use due to this exemption not being granted would jeopardize the capabilities of European medical educational facilities, hospitals, and clinics. This would have a significant impact on healthcare quality and treatment outcomes, especially in critical care and point-of-care departments. In addition, employment and operations would be impacted due to direct effect and business-to-business dependencies in areas such as those listed here:

- Werfen Affiliates in EU
- Other medical device manufacturers with headquarters and offices located in the EU and throughout the world (e.g. Radiometer HQ based in Denmark, etc.)
- Roncello, Itally IL facility, where the GEM products and ancillary devices are shipped to/from and stored
- EU local distributors/distribution centers for GEM analyzers
- Logistics and processing of Refurbished units (e.g. replace/rebuild/QC/parts management, etc.)
- Worldwide raw material, and sub-assembly manufacturers
- Worldwide processing service suppliers
- Sales force and Marketing for customers based in Europe
- Technical Support e.g. call center(s) and on-site Service would be impacted
- Hospitals and medical clinics would be adversely impacted due to limitations in analytical capabilities to enable physicians to diagnose and treat ailments.
- Hospital financial budgets would be adversely impacted due to a limited if any selection of currently RoHS compliant options and the changes that could be required in infrastructure which would impact time to make such a transition (e.g. LIS, LIM, revalidations, etc.)

d. Please estimate additional costs associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).

Answer from Instrumentation Laboratory: If the exemption is not granted, then it will become challenging for hospitals and other medical care facilities to have these critical care analyzers to diagnose and treat patients that assure exceptional outcomes from well-equipped healthcare institutions. This scenario is guaranteed to impose great liabilities on medical practitioners limited in analytical measurement systems and consequently data to interpret for an accurate diagnosis and treatment plan. For the patient, this means a substantially higher margin for error by physicians to make good medical

decisions to provide the proper care and sustain life. Consequently, patients with diminished health may not be able to aptly perform their job functions or care for themselves and family members due to the compromised quality of healthcare that would be possible without these medical equipment providing critical information.

- Based on an estimated total of greater than 19,000 analyzers by all manufacturers placed in the EU, this accounts for approximately 282,159,600 tests.
- In the EU-28, the population total was 508,401,000 based on information sourced from *"Population on 1st January by age and sex". Eurostat*. Retrieved *14 June* 2017. *(http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=proj_15npms&lang=en)*

In conclusion, an exemption not being granted will assuredly impact health and safety. Therefore, the societal and economic magnitude is much larger for not permitting these medical devices than permitting their use while manufactures continue to explore and pursue RoHS compliant solutions.

4. The application refers to an LCA prepared to support this request for exemption renewal.
   The summary explains that two other sensors using organic based stabilizers were compared with the current sensors. Please confirm that the two alternative sensor cards are identical aside from the stabilizer used (i.e. in terms of PVC being the sensor card material and in terms of the various functions built into the card and the substances and materials used therefore).

   Answer from Instrumentation Laboratory: Yes, they are identical except the stabilizer used. As noted in our application, these alternatives are not commercially viable options to replace the current based on the observed performance and results.

5. In the previous evaluation of this exemption, it was established that other equipment, such as the i-STAT of Abbott Laboratories, use sensor cards comprised of silicon.
   a. Please explain if other materials have been considered as alternatives to the PVC cards, so as to eliminate the need for lead?

      Answer from Instrumentation Laboratory: Yes, during early product development phase of the GEM analyzers, other sensor designs have been considered for suitability towards GEM sensor development. Based on various (system, manufacturing, stability, quality, and performance) requirements and metrics, PVC has been chosen as the substrate for GEM sensor development.

b. If research has been conducted in this direction please summarize results.

Answer from Instrumentation Laboratory: PVC based substrate has been the primary basis for the sensor technology used in the GEM Premier analyzers. PVC based substrates provide several technical advantages over silicon based substrates used in I-STAT type platforms. For example, PVC based substrate provides excellent sensor stability for multi-use operation. Sensors used in GEM-like blood gas analyzers have excellent adhesion with PVC substrate and provide the necessary stability for multi-use operation up to 600 measurements. Based on its stability for multi-use, all GEM sensors are 100% factory tested prior to shipment to provide quality sensors at customer use. Silicon based substrates provide poor adhesion to PVC based ion selective electrodes and for that reason they are traditionally used for single use tests.

In addition, multi-use capability of GEM sensors and cartridges provide critical care analyzers with faster time to results, continuous analysis of patient samples in a lab or point of care setting (up to 600 samples or 31 days of use-life) without having the need to change cartridges for each assay. These benefits enhance the ability for hospital staff to take care of patients. Multi use-sensors used in GEM-like systems typically have a lower cost per test compared to single-use sensors thereby providing economic value to healthcare institutions.

Sensor technology used in GEM or other multi-use blood gas analyzers are designed to meet several functional, performance or customer expectations and these technologies are proprietary to each manufacturer's designs. Based on the advantages listed above, the historical experience with PVC substrates and the complex nature of sensor technology, Instrumentation Laboratory continued to explore options to optimize around the PVC without lead-based thermal stabilizers rather than redesign the sensor using other substrate options.

c. Otherwise please explain why this approach has not been investigated.

Answer from Instrumentation Laboratory: See answers above.

THE END.

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