When the ESD malfunctions were correlated with the occurrence date (i.e., month), it was found that nearly half of the ESD events occurred during the coldest months of December, January, and February, whereas only 7.7% occurred during hottest months of June, July, and August (see Figure 3). These results could be attributed to lower RH levels in cold months due to indoor heating. Some malfunction reports explicitly noted that low RH at the event location was a contributing factor for charge accumulation and the subsequent ESD events. More statistical analysis should be conducted in this area.

IV. ENVIRONMENTAL INFLUENCE ON ESD EVENTS

The risk of ESD events is dependent on the moisture in the air. Moisture contributes free charge carriers and lowers surface resistivity of materials, resulting in reduced charge buildup and faster dissipation of the accumulated charge to the ground. In electronic assembly areas, the recommended minimum level for RH is 30% [19]. The instruction for use (IFU) of many medical devices provide specifications for the minimum operating RH level (most commonly 30% RH), to minimize charge buildup and consequent ESD malfunctions of the device. However, humidity guidelines for medical facilities are more concerned with infection transmission, rather than ESD malfunction of electronics [20].

Some ESD malfunction reports explicitly noted that the RH at the event location was lower than 30%, i.e., the minimum RH recommended in the IFU of the device. These devices include clinical chemistry analyzers (764 reports), heart-lung machines (8 reports), a heart assist device, a ventilator, a coagulation analyzer, a tissue processor and an aspiration pump. The majority of these devices are stationary medical devices that were used in a hospital room where RH was most likely controlled above a minimum limit to provide comfort for the staff. A possible reason for the low RH could be that the ventilation system was not active at the time of the event, or the RH level was set to a value lower than 30%.

In 2010, the Addendum D to ASHRAE 170 standard [21], titled "ventilation of healthcare facilities" lowered the original minimum 30% RH level in critical care areas to 20%, primarily to minimize humidification costs. For example, we estimated that a hospital in Nevada would save over $10,000 per year by implementing this standard. However, the minimum RH level of 20% is not compatible with the RH requirements of most microelectronic devices [22], since higher voltage ESD events are directly related to lower RH values. Unfortunately, this standard has been adopted by several key federal regulatory organizations such as the Centers for Medicare and Medicare Services (CMS), which issued a waiver in April 2013 that permits hospitals to keep RH level of critical care areas above 20% [23]. The ASHRAE 170 standard has still not updated its minimum RH level for critical care areas. A newer categorical waiver by CMS [24] instructed hospitals to ensure compliance of the new minimum RH limit with the instruction for use of the medical equipment in the facility, before electing to use the previous waiver [23].

V. CONCLUSIONS AND RECOMMENDATIONS

Despite the long history of ESD considerations in the electronics industry, our analysis shows that manufacturers of medical devices do not implement adequate ESD prevention. Furthermore, the number of malfunction reports, recalled devices and patient complications indicate that ESD immunity standards for medical devices may not be adequate, including those specified in IEC 61000-4-2.

Medical device manufacturers need to implement ESD mitigation programs to prevent device malfunctions. The failure mode, effect and criticality analysis (FMECA) [25], [26] is one method to classify all possible failure modes based on their associated risks. In an FMECA procedure, a criticality index is assigned to each failure mode caused by ESD, such as frozen display or date and time reset, and a criticality index is calculated based on the severity of the effect of each failure mode and their probability of occurrence. The severity should depend on patient complications, noting that both recoverable (e.g., data corruption) and non-recoverable malfunctions (e.g., device shut down) can result in patient injury or death.