

As a medical device manufacturer, Pride Mobility Products Corporation is obligated to report any complaint that alleges deficiencies related to the safety, effectiveness or performance of a medical device in the field to the FDA as well as any applicable government body (i.e. Health Canada, MHRA, TGA, Ministry of Health, etc).
The following list depicts the key words to consider when reporting an alleged incident to Pride:

Key Words	Notification Protocol
Broken Weld	Only notify Regulatory when: <ul style="list-style-type: none"> injury occurred medical attention was sought relating to failure catastrophic failure occurred
Broken Wood	Only notify Regulatory when: <ul style="list-style-type: none"> injury occurred medical attention was sought relating to failure
Burning smell	No
Death	Yes – Notify Regulatory
Fire	Yes – Notify Regulatory
Injury	Yes – Notify Regulatory
Loss of Control/ Unintended Movement	Only notify Regulatory when: <ul style="list-style-type: none"> injury occurred medical attention was sought relating to failure
Melted/Burnt Electrical Connections	Yes – Notify Regulatory
Smoke	Only notify Regulatory when: <ul style="list-style-type: none"> injury occurred medical attention was sought relating to failure
Sought Medical Attention (Paramedic/Fire Dept./ER/Doctor, etc.)	Yes – Notify Regulatory
Spark	Yes – Notify Regulatory
Tip Over/ Flipped Over	Yes – Notify Regulatory

All Providers must report alleged incidents as follows:

- Reports of alleged incidents ***within 30 days of becoming aware*** to: **Kim Elmes, Verification Manager, Quality Management Systems, x3028, or kelmes@pridemobility.com.**
- Reports of litigation issues to: **Lisa Tighe, Litigation and Claims Service Manager, x1306 or ltighe@pridemobility.com.**

All other service related questions can be directed to the appropriate Technical Service Department.