

	<i>Document Title, Revision No.</i> <b>MDR Procedure, Rev. 001</b>
	<i>Approved by:</i>
	<i>Approval date:</i>

1. **Purpose:** To ensure that complaints are evaluated in a timely and effective manner for the purpose of identifying and reporting MDR eligible events.
2. **Scope:** This procedure is applicable to all employees who receive information regarding an product malfunction, or a patient injury or death reported to be associated with a product. It is used as a companion to the Complaint Investigation procedure.
3. **Procedure:**

### 3.1 MDR Reporting

**3.1.1 MDR status determination** – The reportability of an event is determined by use of the Complaint Investigation Form, in which prompts the user to complete a MedWatch form (FDA Form 3500A) under condition of:

**3.1.1.1 Malfunctions known to have been associated with patient injury or death within the previous two years.**

**3.1.1.2 Malfunctions resulting in patient injury.**  
Patients are considered injured by report or if any type of medical intervention is required as the result of malfunction or suspected malfunction.

**3.1.1.3 Malfunctions resulting in patient death.**

**3.1.2 MedWatch form completion** - Information regarding MDR reportable events are submitted to FDA for review on MedWatch forms.

**3.1.2.1.1** MedWatch forms must be typed or completed with FDA provided software instead of hand written.

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3.1.3 **30-Day Deadline** – MedWatch forms must be completed and postmarked within 30 days of any Alpha Industry employee receiving information regarding an MDR reportable event.

3.1.4 **5-Day Deadline** – MedWatch forms must be completed and postmarked within 5 days of any employee receiving information regarding an MDR reportable event where the manufacturer initiates remedial action to protect public health (such as a recall), or which is specified in writing by FDA to the company as reportable within 5 days.

3.1.5 **Baseline reports** – A Medical Device Reporting Baseline Report (Form FDA 3417) is submitted with the MedWatch form for the first reportable event associated with each device model.

**3.2 MDR Submission** – MedWatch and baseline reports are submitted to the FDA via certified mail, per the instructions on the form.

**4. Records:**

**4.1 MDR file contents** – MDR files are maintained as complaint files, with the addition of:

- 4.1.1 A copy of the submitted MedWatch form(s)
- 4.1.2 A copy of the submitted baseline report (when applicable)
- 4.1.3 All customer correspondence relevant to the event
- 4.1.4 All FDA correspondence relevant to the event
- 4.1.5 Certified mailing slips and returned receipts

**4.2 MDR file location** – MDR files are maintained in hard copy format as a part of the complaint filing system.

- 4.2.1 MDR files are visually identifiable within the complaint filing system by a permanent red marker or label.

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**4.3 MDR file maintenance** – MDR files are maintained for a period of 2 years after the date of event.