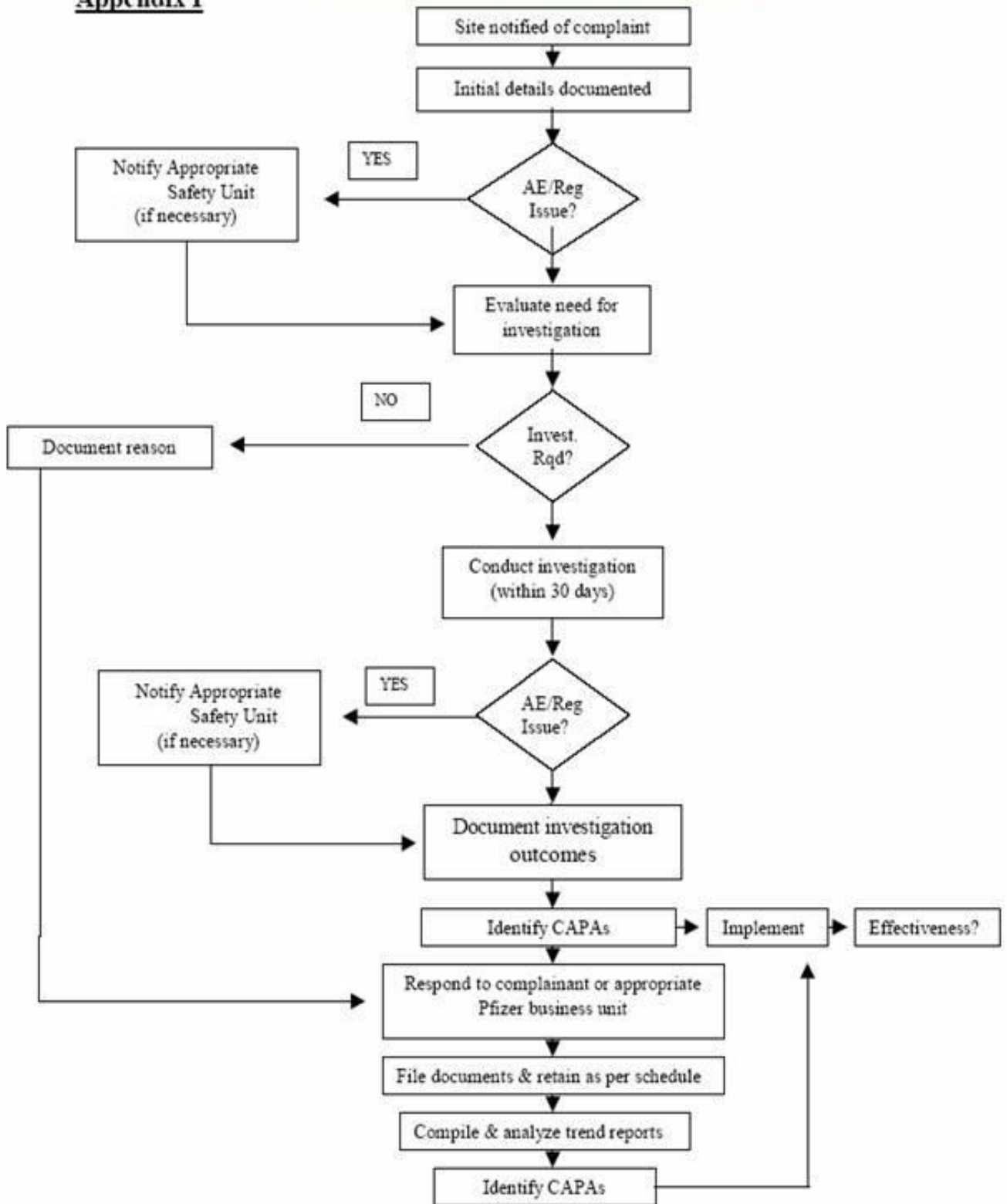


Guidance Number 060:

Appendix I

COMPLAINT FLOW DIAGRAM



Appendix II - Product Quality Complaint - Contact Summary Sheet

Date of Call: _____	Contact Name: _____
Complaint Number: _____	
Complainant Name(s): _____	
Complainant Phone Number: _____ (Home or Work)	
Address: _____	

Product Name: _____ Product Strength: _____

Product LOT NUMBER: _____ Product Expiration Date: ____/____/____

Complaint Classification: _____ Complaint Sub-Classification: _____

Complaint: _____

Additional Comments: _____

Device MODEL NUMBER: _____ Device LOT NUMBER: _____ Expiration Date: ____/____/____

Complaint: _____

Additional Comments: _____

Product Return Requested (Yes or No): _____ Device Return Requested (Yes or No): _____

Return Status (Forthcoming, Not Available, Received): _____