Assignment

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RGA6233 – Applications of QSR in Medical Devices

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RadHealth, Inc.

StrokeMate: AI-Enabled CT Imaging System for Acute Neurovascular Event Detection

Contents

RadHealth, Inc.	Document Number: SOP-QMS-001	Revision #: 1.0
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Title: Document and Records Control		
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SOP-QMS-001: Document and Records Control

Document Number	SOP-QMS-001
Version	1.0
Effective Date	02/22/2026
Owner	Director, Quality Assurance (QA)
Periodic Review	02/22/2027 (annual, or upon regulatory change)

Purpose

This Standard Operating Procedure establishes the requirements for creating, reviewing, approving, distributing, revising, and retiring controlled documents and quality records at RadHealth, Inc. The intent is to ensure that only current, approved documents are available at points of use, and that all quality records remain legible, retrievable, and protected from loss, damage, or unauthorized modification throughout the document lifecycle.

Scope

This SOP applies to all controlled documents and records generated or maintained by RadHealth, Inc., including the Quality Manual, Standard Operating Procedures, Work Instructions, forms, templates, Design History Files, Device History Records, complaint records, and regulatory submission documents. All RadHealth employees who create, review, approve, distribute, or use controlled documents are subject to this procedure.

Definitions

Controlled Document — Any document governed by the RadHealth quality management system that requires formal review, approval, version control, and access management.

EDMS — Electronic Document Management System – the RadHealth software platform used to store, version-control, and distribute all controlled documents.

MDL	Master Document List – the official register of all current approved controlled documents, maintained by the Document Control Coordinator.
DCR	Document Change Request – the formal form used to initiate a revision to any controlled document.
Obsolete Document	A superseded version of a controlled document that is no longer approved for use.
Quality Record	A completed document providing objective evidence of activities performed or results achieved under the quality management system.
Designee	An individual formally assigned in writing by the role holder to act on their behalf for a specific defined activity. Designee assignments must be documented and filed with the Director of QA prior to taking effect.

Responsibility and Authority

Director, QA	Owns this SOP; holds final approval authority for all controlled documents; reviews and approves all DCRs; ensures the EDMS is maintained and accessible.
Document Control Coordinator (QA Staff)	Logs and assigns document numbers; maintains the MDL; distributes approved documents; archives and removes obsolete documents; tracks open DCRs.
Department Managers	Initiate DCRs for documents within their area; ensure employees use only current approved documents; confirm training is completed before revised documents take effect.
Document Author	Prepares draft documents; coordinates stakeholder review; resolves reviewer comments; submits final draft for approval.
All Employees	Use only current approved documents; report document discrepancies or errors to their Department Manager or directly to the Document Control Coordinator within one (1) business day of discovery.

Procedure

Document Numbering and Initiation

The Document Author identifies the need for a new controlled document and notifies the Document Control Coordinator. The Document Control Coordinator assigns a unique document number using the following convention: SOP-QMS-XXX for Quality Management System SOPs; SOP-ENG-XXX for Engineering SOPs; SOP-RA-XXX for Regulatory Affairs SOPs; WI-XXX-XXX for Work Instructions; FRM-XXX-XXX for Forms; and LOG-XXX-XXX for Logs and registers. The Document Control Coordinator logs the new document number, title, assigned author, and initiation date in the MDL with status *In Draft*. The Document Author prepares the draft using the approved

RadHealth document template and watermarks all draft pages *DRAFT – NOT FOR USE* until formal approval is granted.

Stakeholder Review

Upon completing the draft, the Document Author distributes it to all identified stakeholders via the EDMS review workflow. Stakeholders must include all personnel who will execute the procedure. Each stakeholder has seven (7) business days to submit written comments. Failure to respond within this window is documented by the Document Control Coordinator and treated as no objection. The Document Author reviews all comments, resolves conflicts by consulting the relevant Department Manager, and documents the disposition of each comment in the DCR or in a comment resolution log attached to the draft. If a stakeholder objects to a resolution, the matter is escalated to the Director of QA, who makes the final determination within three (3) business days. Once all comments are resolved, the Document Author updates the draft and submits it for formal approval via the EDMS approval workflow.

Formal Approval

The responsible Department Manager reviews the document for technical accuracy and completeness within five (5) business days of submission. If deficiencies are found, the document is returned to the Document Author with written comments for correction. Upon Department Manager approval, the EDMS routes the document to the Director of QA for final approval within five (5) additional business days. If rejected, written rationale is provided and the document re-enters the correction cycle. Upon approval by the Director of QA, the Document Control Coordinator updates the MDL status to *Approved*, assigns the effective date, and releases the document in the EDMS. The total review-to-approval cycle shall not exceed fifteen (15) business days from initial stakeholder distribution.

Distribution and Access Control

Upon release, the Document Control Coordinator notifies all affected employees via the EDMS automated distribution notification. Employees access current approved documents exclusively through the EDMS. Printed copies are considered uncontrolled unless stamped *CONTROLLED COPY* by the Document Control Coordinator at the time of printing. Controlled printed copies must be returned to the Document Control Coordinator when a new revision is released, at which point the Coordinator destroys or stamps the returned copy *OBSOLETE* and records the disposition in the MDL. External documents referenced in RadHealth SOPs, such as FDA guidances and ISO standards, are listed in the MDL with their version or date accessed, and checked for updates annually during the periodic review cycle.

Training Prior to Implementation

Before a new or revised document takes effect, the responsible Department Manager identifies all employees required to be trained on the document content. Training must be completed and recorded in the RadHealth training management system before the effective date of the document. The Document Control Coordinator shall not release a revised document in the EDMS until the

Department Manager confirms in writing that all required training has been completed. Training records are maintained per SOP-QMS-004 and are subject to audit.

Document Revision

Any employee who identifies the need for a document change submits a completed DCR (Form FRM-QMS-001) to the Document Control Coordinator, describing the proposed change and its rationale. The Document Control Coordinator logs the DCR and assigns it to the responsible Department Manager within two (2) business days. The Department Manager reviews the DCR within five (5) business days and either approves it for action, rejects it with written rationale, or requests additional information from the submitter. If approved, the Document Control Coordinator assigns a new revision level and initiates a new draft following the steps in Sections 5.1 through 5.5 of this procedure. The revision history table within the document is updated to include the revision number, date, description of the change, and the author's name.

Obsolete Document Control

Upon release of a new revision, the Document Control Coordinator immediately archives the prior version in the EDMS obsolete document folder, which is read-only and accessible only to the Document Control Coordinator and the Director of QA. The prior version is marked *OBSOLETE – DO NOT USE* in the EDMS and removed from all active distribution lists. One archived copy of each obsolete document is retained for the full regulatory retention period defined in Section 5.8.

Records Retention

All quality records shall be retained for a minimum of two (2) years from the date of device release to the market, or as required by applicable regulations, whichever is longer. Records shall be stored in a manner that prevents deterioration, loss, and unauthorized access, and shall be legible, uniquely identifiable, and retrievable within one (1) business day upon request. At the end of the retention period, the Document Control Coordinator obtains written approval from the Director of QA before any records are destroyed, and destruction is documented in the MDL.

Periodic Review

The Document Control Coordinator generates a list of all documents due for periodic review sixty (60) calendar days before the review date and distributes it to the respective document owners. Each document owner reviews the document for continued accuracy, completeness, and regulatory compliance, and either confirms no change is needed or initiates a DCR per Section 5.6. The Document Control Coordinator records the outcome of each periodic review in the MDL, including the date of review, the reviewer name, and the disposition.

Related and Support Documentation (Internal References)

- SOP-QMS-002: Corrective and Preventive Action (CAPA)
- SOP-QMS-004: Training and Competency Management

- Document Change Request Form (FRM-QMS-001)
- Master Document List (MDL-001)

External References

- 21 CFR Part 820, Subpart M – Records
- ISO 13485:2016, Clause 4.2 – Documentation Requirements
- 21 CFR Part 11 – Electronic Records; Electronic Signatures

Revision History

Rev	Date	Description	Author
1.0	02/22/2026	Initial release	A. Dave

RadHealth, Inc.	Document Number: SOP-QMS-002	Revision #: 1.0
Effective Date: 02/22/2026		
Title: Corrective and Preventive Action (CAPA)		
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SOP-QMS-002: Corrective and Preventive Action (CAPA)

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Version	1.0
Effective Date	02/22/2026
Owner	Director, Quality Assurance (QA)
Periodic Review	02/22/2027 (annual, or upon regulatory change)

Purpose

This Standard Operating Procedure establishes the process for identifying, documenting, investigating, implementing, and verifying corrective and preventive actions at RadHealth, Inc. The goal is to eliminate the root causes of nonconformities and to prevent their recurrence or initial occurrence, thereby maintaining the safety and effectiveness of the StrokeMate AI-Enabled CT Imaging System and the integrity of the RadHealth quality management system.

Scope

This SOP applies to all CAPA activities arising from internal audit findings, customer complaints, nonconforming product reports, post-market surveillance data, AI algorithm performance deviations, adverse events, management review outputs, regulatory observations, and employee-identified process failures. All RadHealth departments are within scope.

Definitions

CAPA Corrective and Preventive Action. Corrective action eliminates the cause of a detected nonconformity. Preventive action eliminates the cause of a potential nonconformity before it occurs.

Root Cause The fundamental, verified reason a nonconformity occurred. Addressing the root cause prevents recurrence.

AI Performance Deviation	Any unexpected or clinically significant departure of StrokeMate probability score outputs, visual overlays, or structured severity scores from validated performance specifications, identified through post-market surveillance or complaint data.
Effectiveness Verification	Objective, pre-specified evidence demonstrating that implemented CAPA actions have eliminated the root cause and the nonconformity has not recurred within the defined verification window.
Containment Action	An immediate, temporary measure taken to prevent a known nonconformity from causing further harm or product release before the root cause is resolved.
Designee	An individual formally assigned in writing by the role holder. See SOP-QMS-001 for designee documentation requirements.

Responsibility and Authority

Director, QA	Owns this SOP and the CAPA system; reviews and approves all CAPA records at closure; escalates unresolved or overdue CAPAs to senior leadership; presents CAPA trends at Management Review.
CAPA Coordinator (QA Staff)	Logs all CAPAs in LOG-QMS-001 within two (2) business days of receipt; assigns CAPA numbers; monitors open actions and due dates; issues overdue notifications; coordinates effectiveness verification scheduling.
Department Manager / Process Owner	Leads the root cause investigation within their area; assigns action owners and due dates; confirms implementation; submits effectiveness evidence to the CAPA Coordinator.
Lead AI Scientist	Investigates all CAPAs involving AI algorithm outputs, model performance, dataset integrity, or adversarial input events; assesses whether a regulatory submission change is required.
Software Engineering Lead	Investigates all CAPAs involving software defects, cybersecurity events, DICOM integrity issues, or PACS integration failures; assesses regulatory submission impact.
All Employees	Identify and report potential nonconformities or process failures to their Department Manager or directly to the CAPA Coordinator within one (1) business day of observation.

Procedure

CAPA Identification and Submission

Any employee who identifies a nonconformity, process failure, or potential risk completes Form FRM-QMS-002 (CAPA Initiation Form), providing a factual description of the event, the date and location of occurrence, any immediate patient safety concerns, and the reporting employee's

name. The completed form is submitted to the CAPA Coordinator. For events with potential patient safety impact – including any AI output anomaly that may have influenced a clinical decision – the reporting employee additionally notifies the Department Manager and the Director of QA by phone or direct message within two (2) hours of discovery, regardless of time of day.

CAPA Logging and Priority Assignment

The CAPA Coordinator logs the submission in LOG-QMS-001 within two (2) business days and assigns a unique CAPA number in the format CAPA-YYYY-NNN. The CAPA Coordinator, in consultation with the Director of QA and the relevant Department Manager, assigns a priority level as follows. High Priority is assigned when there is actual or potential patient safety impact, including AI output integrity issues that may have affected clinical triage decisions, or any finding that could require an FDA field action; full investigation must begin within one (1) business day of logging. Medium Priority is assigned for device performance nonconformities without direct patient safety impact, systemic process failures, or repeat audit findings; investigation must begin within five (5) business days. Low Priority is assigned for isolated administrative or documentation errors; investigation must begin within fifteen (15) business days. The CAPA Coordinator records the assigned priority, expected investigation start date, and notifies the assigned Department Manager in writing.

Immediate Containment

For High Priority CAPAs, the Department Manager, in coordination with the Director of QA, implements a documented containment action within one (1) business day of CAPA logging to prevent the nonconformity from causing further harm or product release. Containment actions may include temporary suspension of a software function, issuance of a field safety notice to affected sites, or removal of affected device units from service. The containment action and its rationale are documented in the CAPA record. Containment is a temporary measure and does not replace root cause investigation and corrective action. If the containment action requires a change to device software or labeling, the Software Engineering Lead and the Director of Regulatory Affairs are notified immediately to assess whether an FDA submission or field safety corrective action is required.

Problem Definition

The assigned Department Manager prepares a clear, factual problem statement describing what happened, when and where it occurred, how it was discovered, and the actual or potential impact on patients or product quality. The problem statement must be based on objective evidence only; speculation or assumed causes are not included. The problem statement is entered into the CAPA record and reviewed by the Director of QA before root cause analysis begins.

Root Cause Analysis

The Department Manager assembles a cross-functional investigation team appropriate to the nature of the nonconformity. For AI performance deviations, the Lead AI Scientist leads the technical investigation. For software or cybersecurity events, the Software Engineering Lead leads. The

investigation team conducts a systematic root cause analysis using one or more of the following methods: 5-Why analysis, fishbone (Ishikawa) diagram, or fault tree analysis. The method used is documented in the CAPA record. The team identifies all contributing factors and confirms the root cause with objective evidence. Unverified or assumed root causes are not accepted. The confirmed root cause and all supporting evidence are documented in the CAPA record and submitted to the CAPA Coordinator by the Department Manager. If the root cause cannot be determined within fifteen (15) business days of investigation start, the Department Manager submits a written escalation memo to the Director of QA detailing what has been investigated, what remains unknown, and a proposed path forward. The Director of QA determines next steps within three (3) business days.

Action Planning

Based on the confirmed root cause, the Department Manager documents in the CAPA record the corrective actions to eliminate the root cause, any preventive actions to address the same root cause in other processes or products, the name of the action owner for each action, the due date for each action, and the pre-specified effectiveness verification criteria and measurement method. These criteria must be defined at this stage, before implementation begins. The Director of QA reviews and approves the action plan before implementation. If any action involves a change to a controlled document, a DCR is initiated per SOP-QMS-001 before the action is closed. If any action involves a change to software, algorithm configuration, or cybersecurity controls, the Software Engineering Lead and the Director of Regulatory Affairs jointly assess within five (5) business days whether the change triggers a new FDA submission, and the outcome is documented in the CAPA record.

Implementation

Each action owner implements their assigned action by the agreed due date and documents evidence of completion in the CAPA record. The CAPA Coordinator monitors open actions weekly and sends written overdue notifications to the action owner and their Department Manager for any action not completed within three (3) business days of its due date. If an action remains incomplete ten (10) business days past its due date, the CAPA Coordinator escalates in writing to the Director of QA, who determines whether to extend the due date or reassign ownership.

Effectiveness Verification

Upon confirmation that all actions are implemented, the CAPA Coordinator schedules effectiveness verification per the pre-specified criteria defined during action planning. Standard verification timeframes are thirty (30) calendar days post-implementation for High Priority CAPAs, sixty (60) calendar days for Medium Priority, and ninety (90) calendar days for Low Priority. The Department Manager collects objective evidence against the pre-specified criteria and submits a written effectiveness verification report to the CAPA Coordinator. If evidence confirms the root cause has been eliminated and the nonconformity has not recurred, the Department Manager recommends closure. If verification fails, the CAPA Coordinator reopens the record, notifies the Director of QA in writing, and the investigation returns to Section 5.5 with an expanded scope.

Risk Management File Update

Before CAPA closure, the Department Manager reviews whether the confirmed root cause or corrective action introduces any new or changed risk to the StrokeMate device or its users. If a new or changed risk is identified, the Department Manager notifies the Director of Regulatory Affairs, who initiates an update to the device risk management file per ISO 14971:2019 before the CAPA is closed. The outcome of the risk management review is documented in the CAPA record.

CAPA Closure and Trending

The Director of QA reviews the complete CAPA record – including the problem statement, root cause analysis, action plan, implementation evidence, effectiveness verification, and risk management review – and approves closure only when all elements are satisfactory. The CAPA Coordinator updates LOG-QMS-001 to reflect the closure date and the Director of QA approval. The CAPA Coordinator performs quarterly trending of closed and open CAPAs by root cause category, department, device component, and recurrence rate. Trend data is reported to the Director of QA and presented at each Management Review meeting.

Related and Support Documentation (Internal References)

- SOP-QMS-001: Document and Records Control
- SOP-QMS-003: Complaint Handling and Medical Device Reporting
- SOP-QMS-004: Training and Competency Management
- SOP-QMS-007: Internal Audit
- CAPA Initiation Form (FRM-QMS-002)
- CAPA Log (LOG-QMS-001)

External References

- 21 CFR Part 820, Subpart J – Corrective and Preventive Action
- ISO 13485:2016, Clause 8.5.2 – Corrective Action
- ISO 13485:2016, Clause 8.5.3 – Preventive Action
- ISO 14971:2019 – Application of Risk Management to Medical Devices

Revision History

Rev	Date	Description	Author
1.0	02/22/2026	Initial release	A. Dave

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Title: Complaint Handling and Medical Device Reporting		
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SOP-QMS-003: Complaint Handling and Medical Device Reporting (MDR)

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Version	1.0
Effective Date	02/22/2026
Owner	Director, Regulatory Affairs (RA)
Periodic Review	02/22/2027 (annual, or upon regulatory change)

Purpose

This Standard Operating Procedure establishes the process for receiving, recording, evaluating, investigating, and closing all complaints related to the StrokeMate AI-Enabled CT Imaging System, and for determining whether a complaint constitutes a reportable event under FDA Medical Device Reporting regulations. This procedure applies at all hours and on all days, including weekends and holidays.

Scope

This SOP applies to all feedback received by any RadHealth employee from any source – including clinicians, hospital information technology staff, field service representatives, and published adverse event databases – that may constitute a complaint regarding the StrokeMate device. Events within scope include AI output anomalies, software malfunctions, cybersecurity events, PACS integration failures, and any event where device performance may have contributed to a clinical decision error or patient harm.

Definitions

Complaint Any written, electronic, or oral communication alleging deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it has been released for distribution (21 CFR 820.3(b)).

MDR	Medical Device Report – a mandatory report submitted to the FDA when a device may have caused or contributed to a death, serious injury, or malfunction that would likely cause or contribute to a death or serious injury if it recurred.
Serious Injury	An injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or requires medical or surgical intervention to preclude permanent impairment.
Malfunction	The failure of a device to meet its performance specifications or otherwise perform as intended.
AI Performance Deviation	Any unexpected or clinically significant departure of StrokeMate probability score outputs, visual overlays, or structured severity scores from validated performance specifications.
On-Call QA Representative	A designated QA staff member assigned on a rotating weekly schedule to receive and triage complaint notifications outside standard business hours. The current on-call schedule is maintained by the Director of QA and posted in the EDMS.
eMDR	FDA electronic Medical Device Reporting submission system, accessed via the FDA MedWatch portal.
PACS	Picture Archiving and Communication System.
DICOM	Digital Imaging and Communications in Medicine standard.
Designee	An individual formally assigned in writing by the role holder. See SOP-QMS-001 for designee documentation requirements.

Responsibility and Authority

Director, RA	Owns this SOP; makes all final MDR reportability determinations; reviews and approves all MDR reports before submission; receives escalation for all High Priority complaints.
Complaint Coordinator (QA/RA Staff)	Logs all incoming complaints within two (2) business days; assigns complaint numbers; tracks investigations; coordinates complainant notifications; maintains the complaint file and LOG-QMS-002.
On-Call QA Representative	Receives complaint notifications outside business hours; performs initial triage; notifies the Director of RA immediately for any event with potential patient safety impact.
Clinical Affairs Lead	Evaluates the clinical impact of complaints; assesses whether a serious injury or death may be device-related; provides clinical input to the MDR reportability determination.

Lead AI Scientist	Technically investigates complaints involving AI output anomalies; reviews model logs, input data, and output records for the event in question.
Software Engineering Lead	Technically investigates complaints involving software defects, cybersecurity events, and DICOM or PACS integration failures; retrieves audit trail logs.
All Customer-Facing Employees	Recognize all potential complaints; forward to the Complaint Coordinator within one (1) business day; for events with potential patient safety impact, also notify the On-Call QA Representative or Director of RA immediately.

Procedure

Complaint Receipt

Any RadHealth employee who receives information via any channel – including phone, email, service ticket, clinical feedback form, field service log, or published adverse event database – that may constitute a complaint regarding StrokeMate records the date, time, source, and full description of the reported event as communicated by the reporter. The employee does not promise, speculate about, or commit to any findings or outcomes to the reporter at this stage. The complete record is forwarded to the Complaint Coordinator within one (1) business day. For events received outside business hours that involve potential patient harm, death, or an ongoing safety situation, the receiving employee contacts the On-Call QA Representative directly by phone within two (2) hours. The On-Call QA Representative then notifies the Director of RA by phone within one (1) hour and documents all notifications in the after-hours complaint log (LOG-QMS-003), forwarding the complete record to the Complaint Coordinator at the start of the next business day.

Complaint Logging

The Complaint Coordinator logs every received complaint in LOG-QMS-002 within two (2) business days of receipt, regardless of whether the event is ultimately determined to meet the regulatory definition of a complaint. Each complaint is assigned a unique number in the format CMP-YYYY-NNN. The following information is captured at logging: complaint number and date logged; date and time of the reported event; source of the report including name, title, institution, and contact information where available; full description of the event as reported; device serial number and current software version; hospital or clinical site of occurrence; and patient impact as reported. If required information is missing, the Complaint Coordinator documents what is missing and makes one documented attempt to obtain it from the reporter within three (3) business days.

Initial Triage and Priority Assignment

Within three (3) business days of logging, the Complaint Coordinator, Director of RA, and Clinical Affairs Lead jointly evaluate the complaint and assign it to one of three categories. Category 1 (Potential MDR / High Priority) is assigned for any event involving a patient death, serious injury, or device malfunction that would likely cause or contribute to a death or serious injury if it recurred, including any AI output anomaly that may have delayed or misdirected clinical triage

in a stroke patient; full investigation begins within one (1) business day of triage. Category 2 (Non-MDR Quality Event) is assigned for device performance issues without confirmed patient harm; investigation begins within ten (10) business days of triage. Category 3 (Not a Complaint) is assigned when the feedback does not meet the regulatory definition of a complaint; written rationale signed by the Director of RA is documented in the complaint file before the record is closed. For Category 1 events, the Complaint Coordinator notifies the Director of RA, the Clinical Affairs Lead, and the appropriate technical lead in writing within two (2) hours of the triage decision. The Director of RA notifies RadHealth senior leadership of all Category 1 events within one (1) business day of triage.

Immediate Containment

For Category 1 events where an ongoing patient safety risk is identified, the Director of RA and the relevant technical lead jointly determine within one (1) business day whether an immediate containment action is required. Containment actions may include issuing a field safety notice to affected clinical sites, temporarily suspending use of the device at the affected site, or quarantining specific software versions. All containment actions and their rationale are documented in the complaint file. The Director of RA assesses whether any containment action triggers an FDA field safety corrective action reporting obligation.

Complaint Investigation

The Complaint Coordinator assigns the investigation to the Lead AI Scientist for AI output anomalies, or to the Software Engineering Lead for software and integration events. The technical lead conducts the investigation, which includes review of device audit trail logs and AI input/output records for the event date and time, review of DICOM integrity verification records, assessment of whether the event may have been caused by a cybersecurity event or adversarial input, and determination of whether the issue is isolated or potentially systemic across other sites or software versions. The Clinical Affairs Lead provides a written clinical impact assessment addressing whether patient harm occurred, was possible, or can be ruled out based on available evidence. The technical lead documents all investigation findings in the complaint file and submits them to the Complaint Coordinator within thirty (30) calendar days of the date the complaint was logged. If additional time is required, the technical lead submits a written extension request to the Director of RA before the thirty-day deadline, stating what remains outstanding and the revised completion date.

MDR Reportability Determination

The Director of RA reviews the investigation findings and the clinical impact assessment for every Category 1 complaint and for any Category 2 complaint where patient harm cannot be definitively ruled out. The Director of RA makes a written reportability determination documented in the complaint file, concluding either that the event is MDR reportable with the applicable reporting window identified, or that the event is not MDR reportable with written rationale. The thirty (30) calendar day reporting window applies for events where the device may have caused or contributed to a serious injury or death. The five (5) calendar day reporting window applies when remedial action is necessary to prevent an unreasonable risk of substantial harm to the public, per 21 CFR 803.53;

the Director of RA notifies the Complaint Coordinator immediately upon determining a five-day report is required. The Complaint Coordinator prepares the draft MDR report using the FDA eMDR form, incorporating the investigation findings and the clinical impact assessment. The Director of RA reviews and approves the draft before submission. No MDR report is submitted without the written approval of the Director of RA. The Complaint Coordinator submits the approved report via the FDA MedWatch eMDR portal within the applicable deadline and retains a copy of the submitted report and submission confirmation in the complaint file.

Corrective Action Initiation

If the investigation identifies a device deficiency, the Complaint Coordinator initiates a CAPA per SOP-QMS-002 by completing Form FRM-QMS-002 and submitting it to the CAPA Coordinator within two (2) business days of the investigation being accepted by the Director of RA. The complaint record and CAPA record are cross-referenced in both LOG-QMS-002 and LOG-QMS-001.

Complainant Notification

Within five (5) business days of the Director of RA accepting the investigation findings, the Complaint Coordinator contacts the original reporter to communicate the general nature of the findings, unless legal counsel or the Director of RA has determined that disclosure would be premature pending regulatory reporting or litigation. The complainant notification is documented in the complaint file, including the date, method of communication, the name of the person notified, and a summary of what was communicated. If the complainant requests the return of any device data or sample, the Complaint Coordinator coordinates with the Director of RA before releasing any materials. Complaint samples or device logs are retained for a minimum of thirty (30) calendar days from the date of investigation completion.

Complaint File Closure

The Director of RA reviews the complete complaint file before closure, confirming that all required activities have been completed and documented. The Complaint Coordinator updates LOG-QMS-002 to record the closure date and Director of RA approval. Complaint files are retained for a minimum of two (2) years from the date of device release to market per 21 CFR 820.198(g) and are available for FDA inspection within one (1) business day upon request.

Complaint Trending

The Complaint Coordinator performs a written quarterly trend analysis of all complaints, categorized by complaint type, device software version, clinical site, root cause where determined, and MDR reportability outcome. The trend analysis is submitted to the Director of RA within fifteen (15) calendar days after the end of each calendar quarter. Any trend indicating a pattern of AI performance deviations, cybersecurity events, or recurring software failures is escalated by the Director of RA to the Director of QA for CAPA initiation regardless of individual complaint priority. Complaint trend data is included as a standing agenda item at all Management Review meetings.

Related and Support Documentation (Internal References)

- SOP-QMS-001: Document and Records Control
- SOP-QMS-002: Corrective and Preventive Action (CAPA)
- SOP-QMS-004: Post-Market Surveillance
- Complaint Intake Form (FRM-QMS-003)
- Complaint Log (LOG-QMS-002)
- MDR Submission Checklist (FRM-RA-001)
- After-Hours Complaint Log (LOG-QMS-003)

External References

- 21 CFR Part 820, §820.198 – Complaint Files
- 21 CFR Part 803 – Medical Device Reporting
- 21 CFR 803.53 – Five-day MDR reporting
- ISO 13485:2016, Clause 8.2.2 – Complaint Handling
- FDA Guidance: Medical Device Reporting for Manufacturers (2016)
- FDA MedWatch eMDR: https://www.fda.gov/safety/medwatch

Revision History

Rev	Date	Description	Author
1.0	02/22/2026	Initial release	A. Dave