National Agency for Food & Drug Administration & Control (NAFDAC)

POST-MARKETING SURVEILLANCE (PMS) DIRECTORATE

Guidelines for Post-Market Surveillance and Reporting of Medical Devices and In Vitro Diagnostics (IVDs) Adverse Events, Incidents, Field Safety Notices (FSNs), and Field Safety Corrective Actions (FSCAs)

Foreword

The National Agency for Food and Drug Administration and Control (NAFDAC) is mandated to safeguard public health by ensuring that the circulation of medical devices and in vitro diagnostics (IVDs) are safe, effective, and of good quality. Post-Market Surveillance (PMS) plays a critical role in this mandate by monitoring the performance of these devices once they are on the market.

These guidelines have been developed to provide a structured and transparent process for the reporting, assessment, and communication of adverse events, incidents, and corrective actions related to medical devices and IVDs. It is intended for manufacturers, authorized representatives, importers, distributors, and healthcare professionals.

We urge all stakeholders to familiarize themselves with this document and actively participate in strengthening the PMS system. A culture of timely reporting, risk communication, and preventive actions will go a long way in improving patient safety and ensuring public confidence in regulated products.

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Director General, NAFDAC

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1.0 Introduction

Post-Market Surveillance (PMS) refers to all activities carried out by regulatory authorities and stakeholders to monitor the safety and performance of medical devices and IVDs once placed on the market. It enables the detection of previously unrecognized risks and supports timely interventions.

2.0 Scope and Objectives

This guideline applies to all classes of medical devices and IVDs approved by NAFDAC for use in Nigeria, with the objectives:

- To define procedures for reporting adverse events and incidents and implement timely corrective and preventive actions.
- To ensure timely submission and review of FSNs and FSCAs
- To promote a risk-based approach for post-market oversight to improve patient safety and protect public health.

The Scope includes Adverse Event (AE) and Incident Reporting on:

- Trend Reporting
- Field Safety Corrective Actions (FSCA)
- Field Safety Notices (FSN)

3.0 Legal and Regulatory Basis

This document is guided by:

- NAFDAC Act Cap N1 LFN 2004
- NAFDAC Medical Device Regulations 2025
- WHO Global Model Regulatory Framework
- GHTF and IMDRF PMS principles

4.0 Definitions and Terminologies

- **Adverse Event**: Any undesirable experience associated with a medical device or IVD use.
- **Serious Incident**: An event that led to or might lead to death or serious deterioration of health.
- **Field Safety Notice (FSN)**: Communication from a manufacturer/distributor to users about an FSCA.
- **Field Safety Corrective Action (FSCA)**: An action taken to lower the risk of death or serious health deterioration related to the use of a medical device.
- **Incident**: Malfunction or deterioration in the safety, quality, or performance of a medical device made available on the market, any inadequacy in the information supplied by the manufacturer, and undesirable side effects. **Note**: Depending on jurisdictions, the term adverse event (in its post-market meaning) and incident can typically be used interchangeably
- **MAH**: Marketing Authorization Holder (Holder of Certificate of Registration)
- **Market Surveillance**: The activities carried out and measures taken by competent authorities (regulatory authorities) to check and ensure that devices comply with the requirements set out in the relevant legislation and do not endanger health, safety, or any other aspect of public interest protection.

- **Post-market Surveillance**: A **systematic process** designed to collect and analyze data on the performance and experience with medical devices after their introduction to the market. **Note:** For the purposes of this document, **post-market surveillance** encompasses all actions taken by the manufacturer, Manufacturer Representatives, Marketing Authorization Holder, and Holder of Certificate of Registration based on the findings from the analyzed field data.

5.0 Roles and Responsibilities

Stakeholder	Responsibility
NAFDAC	Risk assessment, communication, enforcement
Manufacturer	Monitor performance, report events, initiate FSCA
MAH	Liaise with NAFDAC, submit reports to NAFDAC.
Importer/Distributor	Communicate FSNs, maintain distribution records.
Healthcare Provider	Detect and report incidents

5.1. Overview of Responsibilities

Manufacturers are responsible for post-market surveillance, focusing on evaluating feedback. Marketing Authorization Holders (authorized representatives, distributors, importers) may act on behalf of the manufacturer. Agreements should be in place to ensure timely feedback collection and forwarding, including translation if necessary. Where applicable, MAHs might also need to submit reports to NAFDAC. This collaboration can enhance feedback collection, providing more information on the safety, quality, and performance of medical devices during actual use. MAHs may also investigate feedback as requested by the manufacturer.

6.0 Procedure for Post-Market Surveillance

Manufacturers and their MAHs must have a post-market surveillance plan that includes:

i. Scope of the Post-Market Surveillance Plan

Manufacturers must specify which products the surveillance plan covers, as different devices may require different approaches due to varying risks, market time, and user experiences.

ii. Objectives of the Post-Market Surveillance Plan

Manufacturers should define the objectives of their surveillance plans, including:

- Identifying new hazards or changes in risk acceptability.
- Detecting misuse of the device.
- Observing unforeseen side effects.
- Identifying malfunctions impacting the benefit-risk analysis.

Additional objectives may include assessing usability issues, recurring malfunctions due to maintenance deficiencies, the impact of treatment on patient quality of life, and potential improvements to the device.

iii. Responsibilities

Manufacturers must define responsibilities and ensure resources for post-market surveillance. A competent and independent team should be involved, covering all necessary expertise.

iv. Data Collection

Reactive post-market surveillance should always be in place, with appropriate data sources selected to meet surveillance objectives. This includes actively collecting data from consumer complaints, returns, damages, etc. Data sources must provide reliable and verifiable data.

v. **Data Analysis**

Data collected through post-market surveillance must be analysed to obtain useful information. Qualitative analysis of incidents can inform further quantitative analysis, such as trend analysis, which requires sufficient data over a long period.

6.1. Risk Management and Other Processes

The data collected and analysed through post-market surveillance should be integrated into other processes such as risk management, quality improvement, and clinical evaluation. This document focuses on using post-market surveillance data in risk management. By leveraging this data, manufacturers can draw conclusions about changes in risk, the need for modifications to a medical device, or the necessity for additional clinical data.

6.2. Implementing Required Actions

Based on post-market surveillance data in other processes, manufacturers may need to take action to address problems or defects related to a medical device. These actions can include:

- **Correction**: Addressing specific problems or defects.
- **Corrective Action**: Removing the cause of nonconformity to prevent recurrence.
- **Preventive Action**: Preventing the occurrence of additional issues.

Manufacturers must evaluate the options to remedy the situation, decide on the appropriate action, and implement it.

6.3. Collecting Feedback

Manufacturers should ensure that users and patients can provide feedback easily. Receiving and acting upon user feedback is a fundamental aspect of post-market surveillance that manufacturers must always perform, regardless of their resources. This involves making feedback submission methods readily accessible and minimizing barriers. Contact details should be clearly visible on the product labelling to facilitate the provision of feedback. Simplifying the feedback process increases the volume of feedback received, providing manufacturers with valuable insights into the device's performance during actual use.

6.3.1. Methods of Collecting Feedback

Manufacturers can consider various methods to collect user feedback, such as:

- **Smartphone Applications**: Apps that allow users to submit feedback directly.
- **QR Codes**: Quick read codes that link to feedback forms.
- **Web Forms**: Online forms that send feedback directly to a database.

6.3.2. Documentation and Analysis

All collected feedback must be documented and analysed promptly. Feedback can be categorized into:

- **Administrative/Contractual Feedback**: Issues related to procurement contracts, such as delivery times, shelf life, and incorrect product quantities.
- **Technical Feedback**: Issues affecting the safety, quality, or performance of the medical device.

While administrative feedback is not typically linked to safety or performance issues, its investigation might reveal potential quality or safety concerns. Therefore, periodic analysis of administrative feedback is encouraged.

6.4. Other Sources of Post-Market Information

Manufacturers should utilize other proactive sources for post-market surveillance, such as:

- **Scientific Literature**: Information on the safety, quality, and performance of the product and similar devices.
- **Production Site and Quality Management System**: Insights from management reviews, nonconforming product rates, and risk assessments.

6.5. Data Sources for Post-Market Surveillance

Manufacturers should select appropriate data sources based on the objectives of their surveillance plan. Possible data sources include:

- Incidents Reported to the Organization
- Maintenance Records
- Installation Records
- Returned Medical Devices
- Medical Device Registries
- Post-Market Clinical Follow-Up (PMCF) Studies
- User Training Feedback
- Advisory Notices
- Scientific Literature
- Market Surveillance Activities by Regulatory Authorities
- Publicly Accessible Databases
- Regulatory Requirements and Standards
- Media
- Medical Device Distribution and Tracking
- Product Quality Information
- Internal Audits and External Inspections

For the equipment that requires regular maintenance, service reports provide insights into performance, such as parts wear and other observations. User training sessions create opportunities to observe users, understand their challenges, and gather feedback on new risks and potential improvements.

Each data source may require specific methods for data collection and analysis. For example, scientific literature requires expert judgment, while maintenance records involve

administrative work. Quantitative analysis can be performed when sufficient data is collected, ensuring high-quality data for analysis.

6.6. Classifying Feedback and Determining Reportability to NAFDAC

Initial Evaluation

All feedback should be evaluated to determine if immediate action is required to protect public health and safety.

Categories of Medical Device Product Problems

Medical device product problems can be categorized as follows (adapted from IMDRF guidance):

No.	Problem Category	Description
A01	Patient-Device Incompatibility Problem	Issues related to the interaction between the patient and the device.
A02	Manufacturing, Packaging, or Shipping Problems	Deviations from documented specifications during manufacture, packaging, or shipping.
A03	Chemical Problem	Deviations from chemical specifications.
A04	Material Integrity Problem	Issues with the durability of the materials used in the device.
A05	Mechanical Problem	Defects in mechanical actions or moving parts.
A06	Optical Problem	Issues affecting the transmission of visible light.
A07	Electrical/Electronic Property Problem	Failures in electrical circuitry.
A08	Calibration Problem	Issues related to the accuracy and calibration of the device.
A09	Output Problem	Deviations in the end result or test results provided by the device.
A10	Temperature Problem	Unintended temperature production by the device.
A11	Computer Software Problem	Issues with software affecting device performance.
A12	Connection Problem	Problems with linking the device for the transfer of liquid, gas, electricity, or data.
A13	Communication or Transmission Problem	Issues with sending or receiving signals or data.
A14	Infusion or Flow Problem	Failures in delivering or drawing liquids or gases as intended.

Table I: Categories of Medical Device product problems

Additional categories include activation, positioning, separation problems, protective measure problems, compatibility problems, contamination/decontamination problems, environmental compatibility problems, installation-related problems, labelling or training problems, human-device interface problems, use of device problems, adverse events without identified device or

use problems, no apparent adverse event, insufficient information, and appropriate term/code not available.

6.7. Reporting Requirements

Manufacturers (or their MAHs) should send an investigation report to NAFDAC under the following circumstances:

- **Serious Public Health Threat**: Immediate reporting, not later than 48 hours.
- **Death or Serious Deterioration in Health**: Report as soon as possible, not later than 10 calendar days.
- **Potential Death or Serious Deterioration in Health**: Report as soon as possible, not later than 30 calendar days.

Additional investigation into the incident may be necessary, requiring further details from the individual providing the feedback.

6.8. Monitoring and Trending Incidents

A system should be in place to monitor the frequency of occurrence or changes in the type/severity of outcomes following incidents. This process, known as trending, should be conducted periodically, e, g. monthly. Based on the analysis, further actions may be necessary, such as changes to manufacturing processes or updates to the Instructions for Use (IFU).

In addition to immediate incident reporting, all feedback should be summarized and reported to the Director PMS periodically, as required by the Medical Device Regulation.

6.9. Internal Feedback

Manufacturers may also receive feedback internally through their quality management system. This feedback typically does not need to be reported to the Agency unless a Field Safety Corrective Action (FSCA) is implemented, as required by the Medical Device Regulation.

6.10. Root Cause Analysis

Manufacturers should investigate feedback to verify it independently and establish the root cause(s). All reasonable efforts should be made to determine if there is a causative link between the medical device and the incident. Root cause analysis helps identify what, how, and why something happened, thus preventing recurrence. A systematic approach should be used to determine an incident's root cause(s). This involves:

- Establishing a methodology for determining causes.
- Identifying all probable causes and their likelihoods.
- Evaluating the evidence for reported causes and likelihoods.

6.11. Deciding if a Correction is Required

Manufacturers must determine if a correction is necessary. A correction refers to any repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to another location. Other corrections might include:

- Additional surveillance of the device in use.
- Retraining users.
- Providing explanations.
- Conducting additional clinical reviews of patients/clients.
- Retesting, if the device is an in vitro diagnostic (IVD).

If the nonconformity poses little risk or is unlikely to recur, the manufacturer may decide only to carry out a correction. Alternatively, the manufacturer might determine that a Field Safety Corrective Action (FSCA) is required, notifying those responsible for the device or affected by the problem through a Field Safety Notice (FSN). In some cases, no action may be necessary.

7.0 Field Safety Corrective Action (FSCA)

7.1. Triggers for FSCA

An FSCA is triggered by information about incidents with distributed medical devices that pose an unacceptable increase in risk. Such incidents may include:

- Malfunctions or deterioration in the safety, quality, or performance of a medical device and IVDs.
- Inadequacies in the information supplied by the manufacturer.
- Undesirable side effects.

7.2. Assessing the Need for FSCA

To assess the need for an FSCA, manufacturers should use risk management principles and activities prescribed within their Quality Management System (QMS). Personnel with appropriate expertise and competency must be consulted to accurately evaluate potential harm and risk.

7.2.1. Possible Actions

FSCA actions may include:

- Returning the device to the manufacturer or its representative (recall).
- Modifying the device.
- Exchanging the device.
- Destroying the device.
- Providing advice on the use of the device.

Device modifications can involve:

- Retrofitting according to the manufacturer's design change.
- Permanent or temporary changes to labelling or IFU.
- Software upgrades, including remote access updates.
- Modifying clinical management of patients to address specific risks.

An FSCA is communicated through an FSN.

7.3. Reporting FSCA

Manufacturers should report any FSCA to the Agency as required by the Medical Devices Regulations. The correct reporting terminology for classification and coding of incidents (Table I) should be used. FSCA reports should include the scope of updates made due to risk management activities. The FSCA final report should include:

- **Final Assessment**: A detailed assessment of the root cause of the problem and proposed corrective actions to reduce recurrence, such as redesign, field updates, improved IFU, etc., along with the progress of implementing these actions.
- **Outcome of Reconciliation**: The results of the reconciliation of the FSCA.

7.4. Field Safety Notice (FSN)

Field Safety Notices are crucial for communicating FSCA and safety information to users. They can also provide updated information on how a medical device should be used. Manufacturers should inform affected users of any FSCA via an FSN and notify the Agency. Typically, affected users receive the FSN through their procurement agents or MAHs, who must inform all users within their supply region. To ensure traceability, manufacturers and MAHs must maintain records of medical devices and their users.

Manufacturers should ensure the FSN is distributed to all affected users and track confirmation of receipt. A detailed distribution list with contact names and email addresses for each recipient must be kept and made available to the Agency upon request.

7.4.1. Content and Format

The FSN should follow a standardized format, written on company letterhead. The FSN should include:

- **Title**: "Urgent Field Safety Notice" on the notice and subject line if sent by email.
- **Intended Audience**: A Clear statement about the intended recipient.
- **Product Description**: Concise details of the product, product code, and lot number(s).
- **Reason for FSCA**: Factual explanation of the problem.
- **Hazard Description**: Clear description of associated hazards and likelihood of occurrence.
- **Recommended Actions**: Actions to be taken by the recipient, including any actions for people previously treated by the affected device.
- **Timeframes**: Where appropriate, include deadlines for actions by the manufacturer and user.
- **Contact Point**: Designated contact for further information.

7.4.2. Notification of FSN to the Agency

Manufacturers should provide a draft of the FSN to the Agency for review, allowing a minimum of 48 hours unless the FSCA dictates a shorter timescale due to safety risks. If prior review is not possible, the Agency should be informed of the FSCA via FSN simultaneously with the affected users.

7.5. Implementing Corrective/Preventive Actions (CAPA)

Based on root cause analysis, manufacturers should consider corrective and preventive actions (CAPA):

- **Corrective Action**: Addressing nonconforming medical devices or preventing recurrence.

- **Preventive Action**: Proactively identifying opportunities for improvement before problems arise.

Sources for identifying preventive actions include:

- Reviews of contracts with key suppliers.
- Supplier surveillance.
- Management review of the quality management system.
- User training programs and job aids.

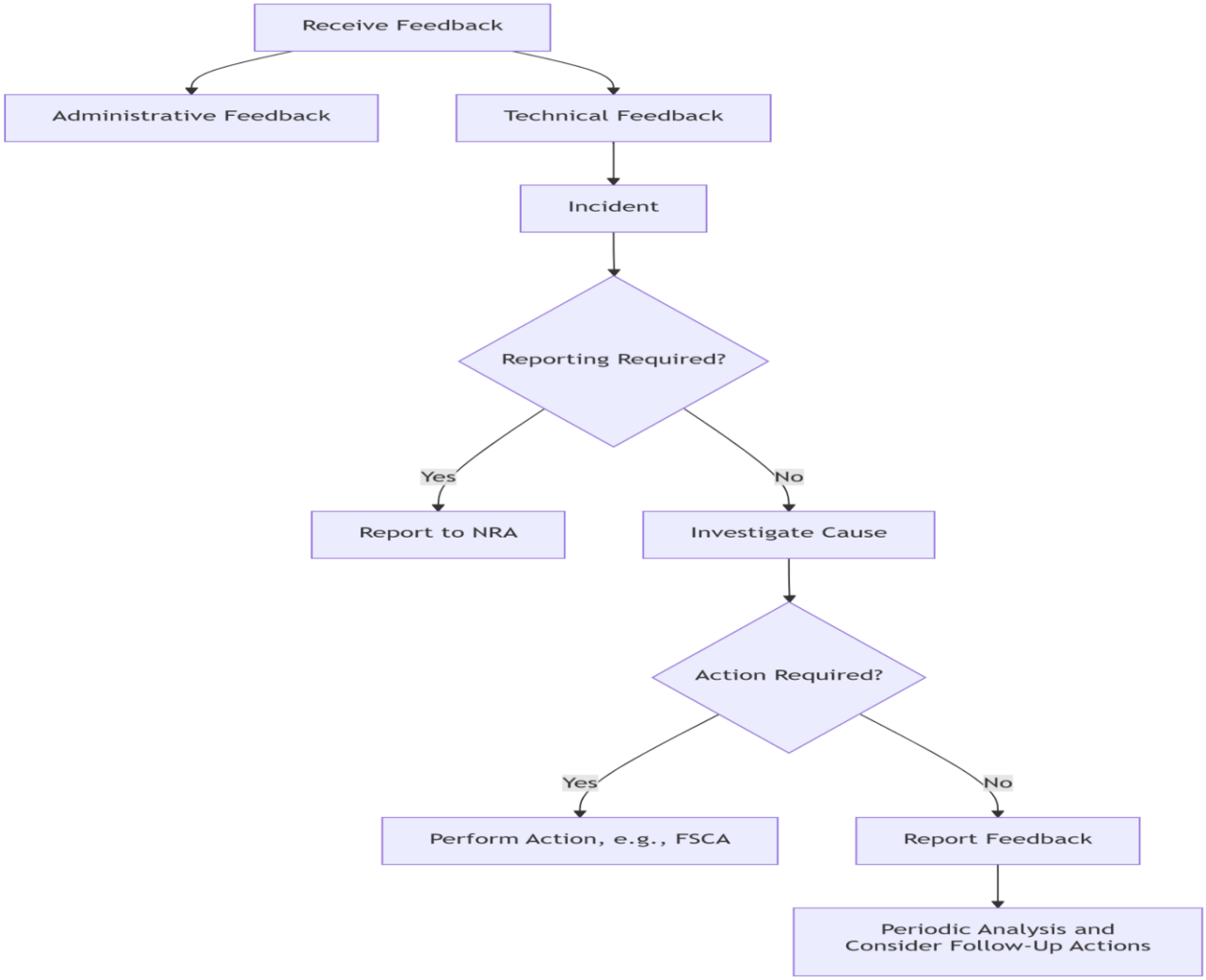
CAPA often involves improvements to the manufacturing process, device design, or quality management system to eliminate causes of nonconformities and prevent recurrence. The systematic investigation of incidents is crucial for identifying effective CAPA. The degree of action should be related to the risk, size, and nature of the problem and its impact on product safety, quality, and performance.

7.6. Reporting and Documentation

Manufacturers should keep all types of reports related to feedback on file, including:

- Initial, follow-up, and final investigation reports.
- Root cause analysis reports.
- CAPA plans.
- FSCA reports.
- FSNs.
- Periodic summary reports.

Schematic Representation



A schematic representation of how manufacturers handle feedback

8.0. Reporting Requirements and Timelines

8.1. Reporting Channels

Reports should be submitted via email to: **pms@nafdac.gov.ng**

8.2. Reporting Timelines

Event Type	Timeline
Serious incident	within 10 calendar days
Death/Serious deterioration	within 2 calendar days
FSCA	immediately upon identification
Final report	Within 30 days of the initial report

8.3. Reporting Format and Forms

Use the NAFDAC Medical Device Adverse Event Reporting Form (see Appendix A).

9.0. NAFDAC's Assessment and Risk Classification Process

NAFDAC classifies reports using risk-based criteria:

- Severity of outcome
- Frequency of occurrence
- Potential population exposed

Each report may trigger inspection, lab analysis, or regulatory action (e.g., suspension, recall).

10.0. Communication of Risk and Corrective Actions

NAFDAC PMS communicates risk through:

- Alerts on its website
- Direct notices to affected users
- Collaboration with healthcare institutions and international

bodies Manufacturers must not issue FSNs before NAFDAC review and clearance.

11.0 Confidentiality and Data Management

All reports are treated confidentially. Only necessary disclosures are made to ensure public safety. Stakeholders are encouraged to report in good faith.

12.0 Enforcement and Sanctions

Failure to comply with the provisions of these guidelines may result in:

- Warning or suspension of registration
- Seizure or recall of products
- Prosecution under relevant laws

13.0 Appendices

Appendix A: Adverse Event Reporting Form Template

(Includes sections for product details, event description, reporter info)

Appendix B: NAFDAC Contact Details

- PMS Directorate

Email: pms@nafdac.gov.ng, sf.alert@nafdac.gov.ng

- Hotline: +234-800-162-3322

Appendix C : Sample FSN/FSCA Format

- Reference number
- Product name
- Description of issue and corrective actions
- User instructions

14.0 References

- **US, FDA 21 CFR Part 803, 806, 822**
- **MHRA PMS Guidance**
- **Health Canada Medical Devices Regulations (SOR/98-282)**
- **TGA PMS Guidance**
- **PMDA/MHLW GVP Guidelines**

APPENDIX C:

FIELD SAFETY CORRECTIVE ACTION REPORTING FORM

Send to:
National Regulatory Authority

1. Recipient details

Date of this report:	
Type of report: ❑ Initial report ❑ Follow-up report ❑ Final report	
FSCA reference number assigned by NRA:	
Name of recipient organization:	
Name of contact person:	Email of contact person:
Street and No.:	City and postcode:
Country:	Telephone:

2. Manufacturer details

Name of manufacturer:	
Street and No.:	City and postcode:
Country:	Telephone:
Name of contact person:	Email of contact person:
Reference number assigned by the manufacturer:	

3. Product details

Product name:
Product code (catalogue number):
Lot number/batch number/serial number:
Expiry date:
Associated devices/accessories (lot numbers/expiry dates):
Instructions for use version number:

Please attach a copy of the instructions for use.

4. FSCA description

Background information and reason for the FSCA:	
Description and justification of action (corrective/preventive):	
Date complaint reported to manufacturer (and/or distributor):	
Advice on actions to be taken by distributor and the user:	
Field Safety Notice attached: ❑ Yes ❑ No	Status of FSN: ❑ Draft ❑ Final
Time schedule for implementation of different actions:	
List of countries this FSCA has been distributed to:	

5. Comments

6. Signature

Name:
Signature:
Date: