OCCURRENCE AND COMPLAINT REPORTING

Scope
Sterile and nonsterile compounding.

Purpose
Define the process by which the pharmacy reports, analyzes and reacts to reported defects and lapses in quality or procedure.

Policy
The pharmacy's policy is to maintain a robust program for the reporting, investigation and resolution of occurrences and complaints. The results of this process will form a key ingredient in the organization's quality management system.

Procedure

Definitions

A. Occurrences, also known as "incidents," are actual or apparent lapses in effectiveness or efficiency that come to the attention of employees other than through routine quality assurance activities.
B. Occurrences include:
    1. Any external complaint, including those from patients, referral sources, prescribers and suppliers.
    2. Adverse patient outcomes.
    3. Product defects.
    4. Equipment problems.
    5. Dispensing errors.
    6. Delivery problems.
    7. Employee injury, infection or exposure.
C. Serious occurrences are defined as:
    1. Significant complaints, best defined by the "upset level" of the aggrieved party and the seriousness of the defect if in fact valid.
    2. All non-trivial adverse patient outcomes.
    3. Significant adverse patient outcomes.
    4. Significant injuries involving employees or patients.
    5. Dispensing errors that reach the patient.
    6. Major financial loss, e.g., waste of an expensive drug.
    7. Employee injury, infection or exposure.
    8. Other defects at the discretion of management.

Reporting

A. The pharmacy encourages the accurate reporting of and appropriate response to occurrences, especially serious occurrences, in the following ways:
    1. Employees are trained on how to report occurrences, whether during regular business hours or after hours, via use of Appendix 50 – OCCURRENCE AND COMPLAINT REPORT (OCR).
    2. A pharmacist reviews for seriousness all OCRs immediately after they are created, and acts accordingly.

OCCURRENCE AND COMPLAINT REPORTING

3. The Pharmacy Manager routinely and systematically solicits from employees information on any unreported recent occurrences to report via routine activities such as daily meetings (see Appendix 1 – DAILY PHARMACY CHECKLIST).
4. Patients are encouraged to report occurrences, including being told how to do so and who to contact.
5. The Pharmacy Manager also initiates an FDA Med Watch or other external reporting if appropriate.
6. Initial Notification
    a) The Pharmacy Manager notifies the Quality Manager of serious occurrences.
    b) The Quality Manager as appropriate notifies external entities or delegates this duty to some other employee. Such outside entities might include prescribers, state boards of pharmacy, and ACHC / PCAB
        1) The following issues are reported to ACHC / PCAB within 30 days of occurrence:
            a. Licensure suspension, probation or limitation.
            b. Non-compliance with Medicare or Medicaid regulations as identified during survey by a regulatory body.
            c. Civil penalties of $10,000 or more.
            d. Revocation of Medicare, Medicaid or other third party provider numbers.
        2) State boards of pharmacy are notified no later than 15 days after initial discovery of a serious occurrence, or as required by them.
        3) All required information need not be available for such notification to be made.

Corrective Actions

A. The Pharmacy Manager or other employee takes immediate corrective actions to remedy the impact of serious occurrences.

Investigation

A. The Pharmacy Manager or his/her designee begins an investigation within 24 hours of initial knowledge if an occurrence involves patient hospitalization or death.
B. Investigation of all other occurrences begins no more than three business days after initial knowledge of the occurrence.
C. Investigations focus upon identifying the root causes of the occurrence and deciding upon the need for further corrective or preventative actions.
D. Further information is gathered as needed.
E. Corrective and preventative actions are either carried out as appropriate or suggested to the Quality Management Committee for further consideration.

Final Notifications

A. Patients, prescribers or other external parties such as state boards of pharmacy are provided the findings of investigations no later than fourteen days after the time of the occurrence.
B. If additional time is required for continued investigation or corrective or preventative actions, external parties are so informed.
C. Prescribers are notified concerning any serious occurrence involving a patient.
D. The Quality Manager is also notified of these findings within the same time frame.
E. The original Occurrence Report or a copy of it is retained by the Pharmacy Manager indefinitely.

OCCURRENCE AND COMPLAINT REPORTING

Coordination and Analysis

A. The Quality Manager serves as the overall coordinator of the occurrence reporting program. He/she also periodically examines reported occurrence information for trends. Trends are reviewed at the next quarterly Quality Management Committee meeting if not sooner.

References and Appendices

PCAB Standards

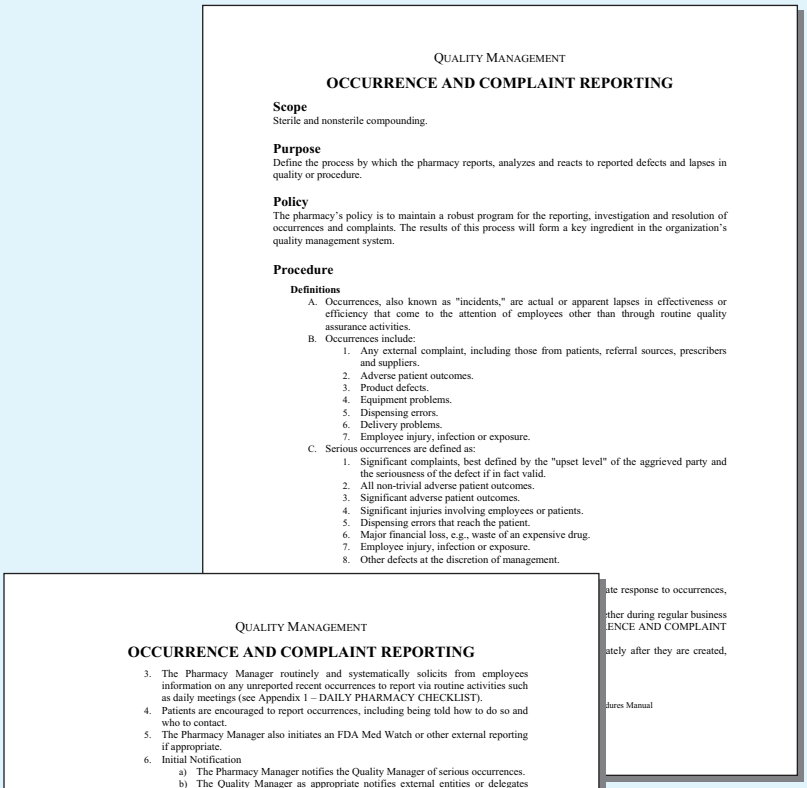
TCRX2-A – Complaint Reporting
TCRX5-E – PI Program-Occurrence Handling
TCRX5-J – PI Program-Complaint Monitoring

Appendices

Appendix 1 – Daily Pharmacy Checklist
Appendix 50 – Occurrence and Complaint Report (OCR)

Compounding Today SOPs

1.069
1.072
9.008
9.048



QUALITY MANAGEMENT

OCCURRENCE AND COMPLAINT REPORTING

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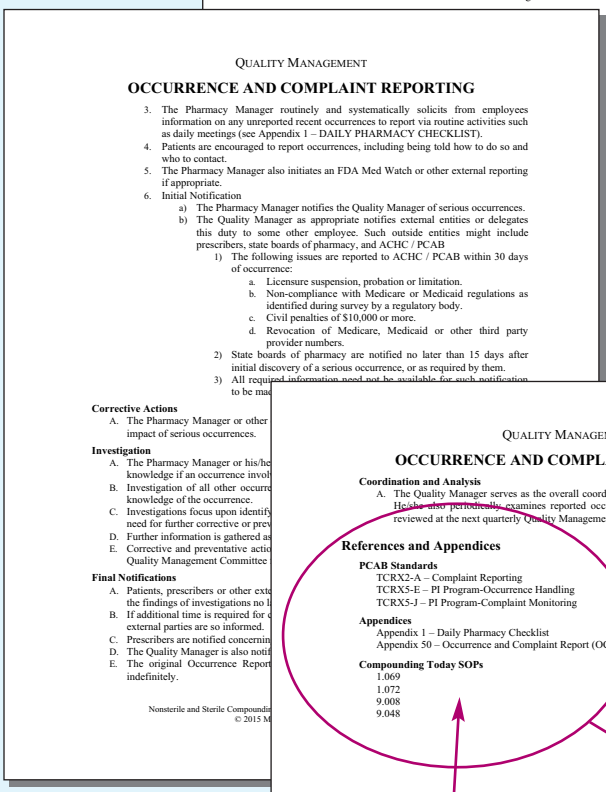

QUALITY MANAGEMENT

OCCURRENCE AND COMPLAINT REPORTING

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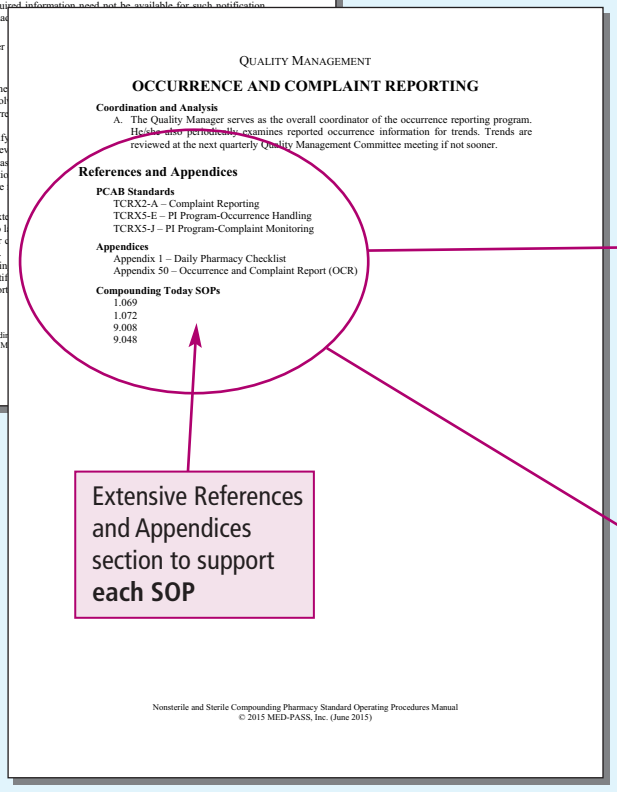

QUALITY MANAGEMENT

OCCURRENCE AND COMPLAINT REPORTING

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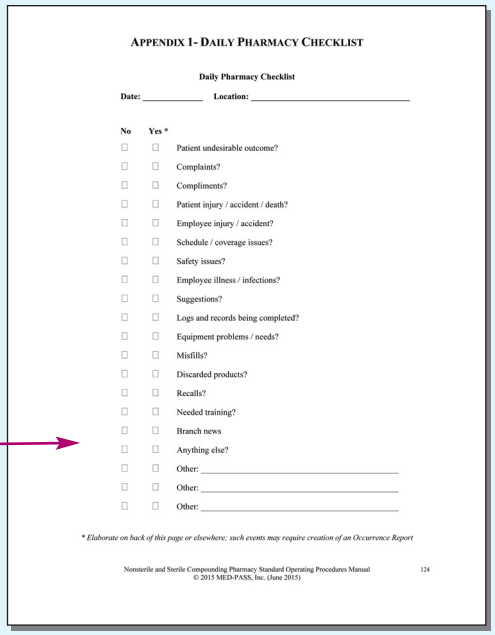
Extensive References and Appendices section to support **each SOP**



APPENDIX 1- DAILY PHARMACY CHECKLIST

Daily Pharmacy Checklist

Date: _____ **Location:** _____

No	Yes *	
☐	☐	Patient undesirable outcome?
☐	☐	Complaints?
☐	☐	Compliments?
☐	☐	Patient injury / accident / death?
☐	☐	Employee injury / accident?
☐	☐	Schedule / coverage issues?
☐	☐	Safety issues?
☐	☐	Employee illness / infections?
☐	☐	Suggestions?
☐	☐	Logs and records being completed?
☐	☐	Equipment problems / needs?
☐	☐	Misfills?
☐	☐	Discarded products?
☐	☐	Recalls?
☐	☐	Needed training?
☐	☐	Branch news
☐	☐	Anything else?
☐	☐	Other: _____
☐	☐	Other: _____
☐	☐	Other: _____

** Elaborate on back of this page or elsewhere; such events may require creation of an Occurrence Report*

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Sample Appendix

Each SOP cross-references current **PCAB/ACHC** standards, appendices and pertinent ***Compounding Today*** policies and procedures.

Features

- Field tested at some of the nation's finest compounding pharmacies
- Incorporates numerous "best practice" suggestions
- Direct references to relevant **PCAB/ACHC** standards and relevant ***Compounding Today*** policies and procedures
- Written with a heavy emphasis on quality control and assurance
- Procedures are ready for implementation, but can be easily customized
- Contains 60 Appendices, including form templates

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