SECTION: Performance Improvement

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I. PURPOSE. The Performance Improvement Plan for Primary Health Care, Inc. (PHC) establishes a planned, systematic, organization-wide approach to process design and performance measurement, analysis and improvement for the health care services and operations we provide.

II. INTEGRATION OF PI PROGRAM WITH MISSION, VISION, VALUES AND STRATEGIC PLAN. This plan will guide PHC staff in fulfilling our mission to be a team of caring professionals providing healthcare and supportive services to individuals in Central Iowa to improve their quality of life. Our vision of being the premiere community health center in the Midwest, respected for providing exceptional care across the life span to a diverse population, will be achieved through ongoing assessment of performance and continuous improvement of our systems of care and service. The strategic plan for PHC outlines our goals and objectives for achieving our mission and vision. We will accomplish these goals through the work of our staff, focusing on core values of integrity, compassion, access, respect and excellence.

In order to accomplish our strategic plan, and achieve our mission and vision, we have established three pillars that support the Mission, Vision and Values (MVV). The People Pillar focuses on staff and community and aligns with our strategic goal of recruitment and retention of staff, board members and community. The Quality Pillar supports our MVV through clinical, safety, program and patient satisfaction initiatives and performance measures. These initiatives/measures align with the strategic goal of expanding and strengthening the value of programs and services. The Performance Pillar focuses on initiatives aimed at ensuring our financial security and stability, through performance measures such as cash collections, visits provided, and patients served. These organizational pillars will guide our performance improvement efforts and help us to achieve our strategic goals and fulfill our mission.

We utilize the analogy of a house to describe this integration. At the base, we have the performance improvement program and information technology to form the foundation of our house. The three pillars – people, quality and performance – provide the support that holds our house together. The roof of the house is our mission, vision, values and strategic objectives, which are supported by the foundation and the pillars. All of these pieces must work together and be integrated in order to make a strong house, and, in other words, a strong organization.

III. GOAL. The goal of the program is to increase the value of our services, by enhancing quality, consistency and strengthening our ability to deliver cost effective care.

OBJECTIVES:
A. To design an effective systematic approach and deployment of processes throughout the organization to meet the needs of our patients which are consistent with the health center's mission, vision, and values.

B. To collect data to monitor the stability of existing processes, identify and develop learning opportunities for improvement, identify changes that will lead to improvement, and sustain improvement.

C. To aggregate and analyze data on an ongoing basis and to identify changes that will lead to improved performance and a reduction in errors.

D. To achieve improved performance and align the improvement throughout the organization.

E. To promote collaboration at all levels of the organization enabling the creation of a culture focused on performance.

F. To educate leaders and staff regarding responsibilities and effective participation in performance improvement activities.

IV. SCOPE AND ORGANIZATION: See Figure 1.

1. **Board of Directors**: The Board of Directors is the final authority and is ultimately responsible for the Performance Improvement Program. It may delegate any and all program operations to the Executive Director of Primary Health Care, Inc.

2. **Performance Improvement Committee of the Board**: The Performance Improvement Committee of the Board is accountable to the Board of Directors for the quality of care and services provided by the health center.

   The Committee identifies and prioritizes improvement opportunities, and ensures that adequate resources are available to accomplish performance improvement initiatives. The Committee receives reviews and evaluates performance improvement reports. The Committee conducts an annual evaluation of the Performance Improvement Program.

   See the Board of Directors Bylaws for more details about this committee. See Figure 1 for reporting structure and Figure 2 for schedule of reports.

3. **Operations Team Performance Improvement Committee**:

   The Operations Team members are responsible for bringing input, information and results from their unit performance improvement meetings
Discussion will occur around designated core measures, including data gathered, tools used, and improvements made. This will allow for sharing, spread of ideas and learning opportunities across units. These ideas and activities will then be carried back to the unit PI meetings for implementation and integration, when appropriate.

The Operations Team Performance Improvement Committee is divided into two groups: the clinic team and the program team with each group meeting on a quarterly basis. On the third month of the quarter, all Operations Team members will meet together to address common PI initiatives and improve performance relating to patient satisfaction, human resources, and safety measures.

The Quality Director, who serves as Chair of the Committee, will act in a facilitative and consultative manner and will assist the Operations Team Performance Improvement Committee in the use of tools, implementation of projects and measuring of results. The Quality Director is responsible to report activities to the Board Performance Improvement Committee on a quarterly basis.

Membership in the Operations Team Performance Improvement Committee will include the following:

See Figure 2 for reporting schedule

<table>
<thead>
<tr>
<th>Members</th>
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<tr>
<td>Quality Director, Chair(C,P)</td>
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<tr>
<td>Operations Director (C,P)</td>
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<tr>
<td>Executive Director (C,P)</td>
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<tr>
<td>Medical Director (C)</td>
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<tr>
<td>Finance Director (AD)</td>
</tr>
<tr>
<td>Dental Director (C)</td>
</tr>
<tr>
<td>MT Clinic Director (C)</td>
</tr>
<tr>
<td>OR/ESC/GV Clinic Director (C)</td>
</tr>
</tbody>
</table>

C = Clinic Team  
P = Program Team  
AD = Ad Hoc

4. **Unit Performance Improvement Committees**: Each unit will have a Performance Improvement Committee which is responsible for implementing the Performance Improvement Program at their

unit/program. Unit PI meetings will be held on a monthly basis. The Unit/Program Director is responsible for these meetings and for reporting to the Operations team Performance Improvement Committee on a quarterly basis as noted above.

The Quality Director will act in a facilitative and consultative manner and will assist the Unit/Program Performance Improvement Committee in the implementation of plans and projects aimed at performance improvement or achieving and maintaining accreditation.

Membership in the Unit Performance Improvement Committee will include all individuals, from all disciplines, from that unit/program. The Executive Director, Medical Director, and Operations Director shall be representatives from the administration team.

Responsibilities of the Unit Performance Improvement Committee will include 1) Utilize performance improvement tools to evaluate, measure, improve and report on core measures at each site. 2) Collect data and monitor improvement on core measures 3) Redesign processes to improve performance that can be integrated at all sites.

3. **Credentials Committee:** The Credentials will meet as necessary to accomplish assigned tasks.

   The Medical Director and the Dental Director serve as Co-Chairs of the subcommittee and, in conjunction with the Executive Director will be responsible for the establishment, implementation, and rigorous review of the clinical competency within the organization’s facilities.

   The responsibilities of the committee include: 1) appointment of licensed independent practitioners to the organization’s medical and dental staff, 2) rigorous and confidential review of the clinical practice of medicine and dentistry by Licensed Independent Practitioners and other clinical staff, and 3) reappointment of licensed independent practitioners by participating in the development, implementation and monitoring of clinical practice guidelines within the facilities.

   If, and when necessary, the committee can be expanded to include all of the organization’s currently privileged licensed independent practitioners.

   Reports will be made to the Board of Directors as necessary.

4. **Other Permanent and Ad hoc Subcommittees or Teams:** The Operations Team Performance Improvement Committee can create
permanent subcommittees, ad hoc subcommittees, performance improvement teams or task forces as needed.

The role of these committees and teams will be to conduct specialized studies in particular areas of concern and submit their findings to the Performance Improvement Committee. Ad hoc subcommittees and teams will be identified in the Performance Improvement committee minutes and will include their charge, a time frame for completion, and suggested dissolution dates. Ad hoc committees and teams may be elevated to permanent status with their inclusion in the appropriate section of the Performance Improvement Plan.

5. **Safety Program – Staff and Patient Safety:** The health center is committed to improving safety for our patients and staff at all sites and centers. This performance improvement plan has incorporated the activities and functions necessary to establish and maintain a comprehensive program for safety and will be implemented at all levels of the organization.

Activities and functions that have been incorporated to address patient and staff safety include:
- Communication with patients about patient safety including patient education and informing patients about their care
- Staff education including related orientation and training and expectations for reporting
- Safety improvement activities listed in the Strategic Dashboard
- Reporting of safety results to staff, committees, executive leadership and governance
- Process for proactive risk reduction and analysis of sentinel events

The Safety Officer is responsible for the organization’s safety program and overall management of the environment of care. Specific job duties are outlined in the Safety Officer job description and include, but are not limited to:

1) establishment, monitoring and maintenance of an effective Environment of Care program,
2) monitoring and evaluating event reports related to safety issues,
3) providing a physical environment free of hazards,
4) reducing the risk of human injury,
5) review and evaluation of each of the environment of care functions to ensure that problems are identified, actions taken and follow up documented,

6) referral of problems to the Operations Team Performance Improvement Committee and/or senior leadership if resolution cannot be accomplished at the Unit PI committee level,
7) annual evaluation of the objectives, scope, performance and effectiveness of the plan,
8) review and approval of safety policies at least every three years, and
9) Joint Commission compliance activities for EOC standards.

Safety Officer will communicate results and recommendations to the appropriate unit manager for resolution. The Operations Team Performance Improvement Committee will review Safety Program reports/activities on a quarterly basis. A summary of these activities will be presented to the Performance Improvement Committee of the Board on a quarterly basis.

6. Infection Control Program

The Infection Control Coordinator is responsible for the surveillance, prevention, and control of infections in the organization.

The responsibilities of the Infection Control Coordinator include:
1) establishment, monitoring and maintenance of an effective Infection Control program,
2) monitoring and evaluating event reports related to infection control issues
3) providing a physical environment free of hazards,
4) reducing the risk of human injury,
5) referral of problems to senior leadership if resolution cannot be accomplished at the Unit PI committee level,
6) annual evaluation of the objectives, scope, performance and effectiveness of the plan,
7) review and approval of infection control policies at least every three years, and
8) Joint Commission compliance activities for IC standards.

The Infection Control Coordinator will communicate results and recommendations to the appropriate unit manager for resolution. The Operations Team Performance Improvement Committee will review Infection Control Program reports/activities on a quarterly basis. A summary of these activities will be presented to the Performance Improvement Committee of the Board on a quarterly basis.

7. Pharmacy and Therapeutics Program:

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The Pharmacy Director will be responsible for the following functions to include: 1) preparation of the health center’s formulary, 2) development of a safe medication management system including policies and procedures relating to selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration and monitoring, and evaluation.

These activities will occur quarterly as part of the Provider Meetings in Marshalltown and Des Moines. Reports are presented to the Board Performance Improvement Committee on a quarterly basis.

V. PERFORMANCE IMPROVEMENT PROCESS

Primary Health Care, Inc. will utilize the following methodology for performance improvement that will integrate the Improvement Model and the Chronic Care Model.

**Improvement Model.** The improvement model consists of three fundamental questions and a Plan-Do-Study-Act cycle to test and implement changes.

![Model for Improvement Diagram]

- **Setting Aims:** An aim is a written statement summarizing what the health center team hopes to achieve. It includes time-specific, measurable goals.
- **Defining Measures:** Measures tell us whether a change we’ve made actually leads to improvement. Measurement should be designed to accelerate improvement, not slow it down.
- **Testing the Change:** All improvement requires changes, but not all changes result in improvement. We will choose changes that seem most promising, and then test them in specific practice settings with specific patient populations.
**Planned Care Model.** The care model is an organizational approach that can be utilized to care for people with chronic disease in a primary care setting. The system is population-based and creates practical, supportive, evidenced-based interactions between an informed, activated patient and a prepared, proactive practice team. The Chronic Care Model emphasizes evidence-based, planned, and integrated collaborative chronic care.

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**Functional and Clinical Outcomes**

**Planned Care Model Change Concepts**

**Health Care Organization**

- Goals for chronic illnesses are a measurable part of the organization's annual business plan.
- Benefits that health plans provide are designed to promote good chronic illness care.
- Provider incentives are designed to improve chronic illness care.
- Improvement strategies that are known to be effective are used to achieve comprehensive system change.

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• Senior leaders visibly support improvement in chronic illness care.

Community Resources and Policies
• Effective programs are identified and patients are encouraged to participate.
• Partnerships with community organizations are formed to develop evidence-based programs and health policies that support chronic care.
• Health plans coordinate chronic illness guidelines, measures and care resources throughout the community.

Self-management Support
• Providers emphasize the patient’s active and central role in managing their illness.
• Standardized patient assessments include self-management knowledge, skills, confidence, supports, and barriers.
• Effective behavior change interventions and ongoing support with peers or professionals are provided.
• Collaborative care-planning and assistance with problem-solving are assured by the care team.

Decision Support
• Evidence based guidelines are embedded into daily clinical practice.
• Specialist expertise is integrated into primary care.
• Provider education modalities proven to change practice behavior are utilized.
• Patients are informed of guidelines pertinent to their care.

Delivery System Design
• Team roles are defined and tasks delegated.
• Planned visits are used to provide care.
• Continuity is assured by the primary care team.
• Regular follow-up is assured.

Clinical Information Systems
• There is a registry with clinically useful and timely information.
• Care reminders and feedback for providers and patients are built into the information system.
• Relevant patient subgroups can be identified for proactive care. Individual patient care planning is facilitated by the information system

VI. IDENTIFYING PERFORMANCE IMPROVEMENT PRIORITIES AND MEASURING PERFORMANCE

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In order to identify and prioritize opportunities for improvement and to effectively and efficiently utilize resources, the health center has established criteria to assist in selection of PI activities.

PI initiatives selected by the health center should meet 3 of the 5 criteria:

1. Consistent with the organization’s mission, vision and values statement
2. Facilitates achievement of the strategic plan
3. Promotes patient safety
4. Addresses needs and expectations of patients and staff
5. Is a high risk, high volume or problem prone activity

The PI Initiatives identified as priorities for this period include:

- Improve the management of our diabetic patients by reducing the number of patients with HgbA1c’s greater than 9
- Improve compliance with updating of patient medication lists
- Improve patient satisfaction of calls returned to patients
- Improved collection of the minimum fee

In addition, we have identified other key areas of performance in our organization which are outlined in the strategic dashboard. These performance measures may change over time as our priorities and strategies change. However, they will continue to align with the three pillars of people, quality and performance.

Data collection will be based on the needs of the organization. Requirements for data collection imposed by funding sources and legal/regulatory agencies will also be included, when appropriate.

The data collected will be used to monitor the stability of existing processes, identify opportunities for improvement, identify changes that lead to improvement, and/or to demonstrate sustained improvement. This data will be collected within the organization’s limited resources.

PHC will use the following sample sizes as guidelines for data collection, which were established because of their statistical significance, their relative simplicity in application, and their sensitivity to the organization’s population size:

- For a population size of fewer than 30 cases, sample 100% of available cases
- For a population size of 30 to 100 cases, sample 30 cases
- For a population size of 101 to 500 cases, sample 50 cases
- For a population size greater than 500 cases, sample 70 cases

The organization will utilize data to make decisions about the performance of the organization. Data will be aggregated and analyzed by the organization in such
a way that current performance levels, patterns, or trends can be identified. The organization will utilize appropriate statistical tools and techniques to analyze and display data.

When appropriate, data will be trended and compared over time. In addition, external sources of information will be used to benchmark the health center’s performance when it is available and appropriate to identify opportunities for improvement.

Analysis will be conducted when data indicates that levels of performance, patterns, or trends vary substantially from those expected and for those topics chosen by the organization as priorities for improvement.

Refer to the Strategic Dashboard for a listing of performance measures and data definitions.

VIII. DOCUMENTATION OF PI ACTIVITIES

PI activities will be documented utilizing a variety of tools and forms.

Teams, committees, subcommittees and task forces will document their activities in the minute format approved by the health center.

In addition, PDSA cycles will be documented on a cycle of change form or on PDSA worksheets. Other forms and tools that may be used to document activities include narrative reports and trend sheets. Templates are available on the network drive in the forms folder. S:\Performance Improvement Program

IX. CLINICAL PRACTICE GUIDELINES. Clinical practice guidelines are used throughout the health center to evaluate and treat specific diagnoses, conditions, and/or symptoms.

Criteria have been established for use in selecting and implementing these guidelines in the health center. The criteria include:

- Diagnoses, conditions, and/or symptoms which are high volume, high risk or problem prone
- Special consideration will be given to guidelines established as part of the BPHC’s Health Disparities Collaborative activities

Clinical practice guidelines currently in use at the health center include: diabetes, HIV, OB and lead testing.

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X. **RISK REDUCTION STRATEGIES.** The organization has defined a process for identification, management, and intensive analysis of sentinel events which is outlined in Appendix C. This process allows the organization to identify root causes for sentinel events that can be addressed on a proactive basis to prevent further injuries.

In addition, the organization will proactively seek to identify and reduce risks to the safety of patients by selecting a high-risk process to be analyzed on at least an annual basis. This will be accomplished through a Failure Mode and Effects Analysis which can be found in Appendix A.

XI. **EDUCATION** Educational needs for performance improvement will be identified by the various teams, committees and subcommittees and will be incorporated into the organization wide training calendar and in other settings as designated by the leaders of the organization. Just in time training of specific Lean and Six Sigma tools will be initiated at the Unit Performance Improvement team meetings.

XII. **PLAN FOR COMPLIANCE WITH JOINT COMMISSION STANDARDS** The health center has an extensive plan to assure on-going compliance with standards. This is outlined in Appendix B.

XIII. **ANNUAL EVALUATION:** The Performance Improvement Committee of the Board is responsible for the annual evaluation of the appropriateness and effectiveness of the Performance Improvement Program. This annual evaluation is accomplished through the efforts of the Operations Performance Improvement Committee. A summary of the annual evaluation is provided to the Board of Directors for review at a Board of Directors meeting.

XIV. **CONFIDENTIALITY:** All information generated as a result of the Performance Improvement Program is considered confidential and will be exempt from subpoena or discovery in accordance with Chapter 147.135 of the Iowa Code.

Discussions in the context of a peer review are completely confidential. This information can only be used within the health center and in the context of valid peer review. Discussion of peer review activities/information in established committees or meetings is protected by law. However, peer review information discussed outside of committee meetings may be considered “discoverable” by the court.

XV. **RESPONSIBILITIES OF STAFF.**

A. **Board of Directors.** The Board of Directors is ultimately accountable for the quality of care and services provided by the health center through the development of a comprehensive performance improvement program.
The Board delegates responsibility for implementation and evaluation of this program through the Performance Improvement Committee of the Board to the Executive Director and management team.

B. **Administrative Team.** The Administrative Team is responsible for implementation and evaluation of the performance improvement program as outlined in the above plan. In collaboration with the Board of Directors, the administrative team aligns the performance improvement activities with the strategic plan and prioritizes improvement efforts.

C. **Directors/Managers.** Directors and managers are responsible for implementation of the PI program for their respective units/clinics/programs. In addition, these managers and directors may serve as chairs, team leaders or as members of committees, subcommittees, teams, and/or task forces. When serving in these roles, consideration of the overall impact on the organization should always be of prime concern.

D. **Medical Staff.** Medical staff members should be familiar with the performance measures and PI initiatives of the health center and their respective unit/program/clinic. Medical staff will be active participants in the performance improvement activities through participation on committees, subcommittees, teams and task forces as appointed. The purpose of this participation is to bring the “front line” perspective to the performance improvement opportunities and initiatives of the health center as well as resolution of problems.

E. **Line Staff.** Staff should be familiar with performance measures and PI initiatives underway for the health center and their specific unit/program/clinic. Staff will be asked to participate in these activities as well as on other committees, subcommittees, teams and task forces as appointed. The purpose of this participation is to bring the “front line” perspective to the performance improvement opportunities and initiatives of the health center as well as resolution of problems.
APPENDIX A

FAILURE MODE
AND EFFECTS ANALYSIS
Objective

To proactively identify and reduce risk to the safety of patients by selecting a high risk process to be analyzed on at least an annual basis.

Definition

FMEA is the systematic analysis of a process to identify the possible ways it might fail, the effects of failures, and the possible causes of failures. The goal of FMEA is to predict how and where systems designed to detect errors fail. If the potential effects of a failure are intolerable, actions are taken to:

- eliminate or minimize the possibility of the error occurring, or
- minimize the consequences of the error when potential error cannot be eliminated.

FMEA is a proactive technique that is most often used to identify and address problems before they occur. In comparison, Root Cause Analysis (RCA), another technique used in analyzing errors, is used retrospectively to address problems after they occur.

FMEA is an ongoing process of quality improvement. Even when improvement is made, efforts to improve processes should continue.

Team Composition

FMEA is most effective when conducted by a multidisciplinary team. When forming the team, include representatives of all disciplines involved in the process being analyzed.

What to Analyze

- Sentinel Event Alert Topics
- High risk or problem prone processes in the organization

Analysis of the Chosen Process

- Ensure that all team members understand the process being analyzed. FMEA requires that a process be tracked from the point of initiation until completion. A flow diagram of the process should be developed.
• Evaluate each step in the process flow diagram to determine what could go wrong with the process (i.e., potential failure modes). Document on the “FMEA Team Member Worksheet” (Attachment A).

• List the effects of the identified failures on the worksheet.

• List the root causes that can produce the failure mode or error on the worksheet.

• Each team member estimates the probability of each failure occurring using a ranking scale below. The team should take into consideration documented reports of the failure in the literature as well as through the event reporting system. Document score on the worksheet.

FMEA Occurrence Ranking Scale

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Category</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Remote</td>
<td>Possible, no known occurrence</td>
</tr>
<tr>
<td>2</td>
<td>Low</td>
<td>Rarely occurs (i.e., yearly)</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Infrequently occurs (i.e., monthly)</td>
</tr>
<tr>
<td>4</td>
<td>High</td>
<td>Frequently occurs (i.e., weekly)</td>
</tr>
<tr>
<td>5</td>
<td>Very High</td>
<td>Almost always occurs (i.e., daily)</td>
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• Each team member estimates the severity of the effects of each failure using the ranking scale below. Document score on the worksheet.

FMEA Severity Ranking Scale

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Category</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No Harm</td>
<td>No harm to patient</td>
</tr>
<tr>
<td>2</td>
<td>Minor</td>
<td>Temporary harm to patient; monitoring or minor intervention required</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Temporary harm to patient; initial or prolonged hospitalization required</td>
</tr>
<tr>
<td>4</td>
<td>Major</td>
<td>Permanent harm to patient</td>
</tr>
<tr>
<td>5</td>
<td>Severe</td>
<td>Terminal injury or death</td>
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</tbody>
</table>

• Each team member estimates the probability of each failure being detected using the ranking scale below. Document score on the worksheet.

FMEA Detection Ranking Scale

<table>
<thead>
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<th>Ranking</th>
<th>Category</th>
<th>Criteria</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Very High</td>
<td>Error will almost always be detected (90-100%)</td>
</tr>
<tr>
<td>2</td>
<td>High</td>
<td>Error frequently detected before reaching patient (70-89%)</td>
</tr>
</tbody>
</table>
### The Risk Priority Number

The risk priority number is the product of the severity, occurrences, and detection. The RPN allows us to prioritize steps toward improvement and focus on the failures that have the highest impact on the customer.

- Calculate the Risk Priority Number (RPN) for each failure mode using the following steps:
  A. Total all team members' scores for frequency of occurrence.
  B. Total all team members' scores for severity of effects.
  C. Total all team members' scores for probability of detection.
  D. Multiply the results of steps A, B, and C (i.e., RPN = A x B x C)

- Assign a RPN for each failure mode by listing in decreasing order of Risk.

- Beginning with the failure modes that have the highest values, identify actions or strategies that could reduce the RPN. Include actions that:
  - decrease the likelihood of occurrence,
  - decrease the severity of effects, and
  - increase the probability of detection.

**Helpful Tip:**
If a large number of failure modes are identified, it is more effective to address the highest rated failure modes initially or re-scope the project to a more manageable process. The rest of the failure modes are addressed later in descending order.

- After possible solutions are identified, the team decides which actions can be implemented without being impractical or significantly affecting the efficiency and effectiveness of the process and action plans along with recommendations are presented to the Operations Team Performance Improvement Committee and communicated to the Board of Directors through the PI reporting structure.

### Implementation of Strategies for Improvement

- Develop an action plan to implement the improvement strategies. See Attachment C.

- Decide if baseline measures of key process issues are needed and complete prior to implementation of the action plan.

- Implement the action plan.
Monitoring/Follow-up
Evaluate the effectiveness of each action taken. Recalculate the RPN of the failure modes to determine if the actions have had an effect. If baseline measures were completed prior to implementation of changes, conduct the measures again and compare to the baselines to determine the effect of the actions.

If the RPN is not reduced for a failure mode or other indicators such as improvement over baseline measures are not improved, the team continues with the FMEA process to identify and implement new improvement strategies. However, even if improvement is found, efforts must be made to continuously improve the process.

Attachment A: FMEA Team Member Worksheet

Primary Health Care, Inc  Failure Mode and Effects Analysis

Name
Goal statement
Date:

<table>
<thead>
<tr>
<th>Created by:</th>
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Disclaimer about this document: http://bphc.hrsa.gov/technicalassistance/resourcecenter/disclaimers.html
<table>
<thead>
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<th>Process name</th>
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<td>Process requirement. The process needs to have the ability to do...(to satisfy the customer requirement)</td>
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</table>

**ATTACHMENT B: FMEA Action Plan**

Process Description: 

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Actions for Improvement</th>
<th>Person(s) Responsible</th>
<th>Target Date</th>
<th>Date Completed</th>
<th>Follow-up Actions</th>
<th>Follow-up Date(s)</th>
</tr>
</thead>
<tbody>
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</table>

Responsibility for Assessment and Compliance with Joint Commission Standards

A. Continuous Readiness and Improvement related to standard compliance:

Team leaders will review Joint Commission Standards for assigned chapter and will assess health center compliance with the standard. On a regular basis, team leaders will report compliance and status of action items at the Operations Meeting and develop action plans and recommendations with the PI Operations Meeting utilizing the following schedule.

**JOINT COMMISSION CHAPTER ASSIGNMENTS**

<table>
<thead>
<tr>
<th>CHAPTER</th>
<th>CLINICAL/ADMINISTRATIVE</th>
<th>Education on Standards At the Operations Meeting</th>
<th>Action Plan Review at the PI Operation Meeting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment of Care</td>
<td>Safety Coordinator</td>
<td>September</td>
<td>All PI Meeting</td>
</tr>
<tr>
<td>Human Resources</td>
<td>Human Capital Coordinator</td>
<td>October</td>
<td>All PI Meeting</td>
</tr>
<tr>
<td>Leadership</td>
<td>Executive Director</td>
<td>November</td>
<td>All PI Meeting</td>
</tr>
<tr>
<td>PI / NPSG’s</td>
<td>Quality Director</td>
<td>December</td>
<td>All PI Meeting</td>
</tr>
<tr>
<td>Information Management</td>
<td>Operations Director</td>
<td>January</td>
<td>All PI Meeting</td>
</tr>
<tr>
<td>Patients Rights</td>
<td>Operations Director</td>
<td>February</td>
<td>All PI Meeting</td>
</tr>
<tr>
<td>Infection Control</td>
<td>Infection Control Coordinator</td>
<td>March</td>
<td>Clinical PI Meeting</td>
</tr>
<tr>
<td>Medication Management</td>
<td>Pharmacy Director</td>
<td>April</td>
<td>Clinical PI Meeting</td>
</tr>
<tr>
<td>Patient Care</td>
<td>Medical Director</td>
<td>May</td>
<td>Clinical PI Meeting</td>
</tr>
<tr>
<td>PPR Review</td>
<td>All</td>
<td>August</td>
<td>All PI Meeting</td>
</tr>
</tbody>
</table>

B. Team Leaders are responsible for initiating and tracking needed improvements. Progress of the specific chapters will be reviewed during the assigned Operations PI Meeting throughout the year. A Team Leader has been identified for each chapter.

Responsibilities of the team leaders include:

- Annual assessment of compliance with current Joint Commission standards, reviewing the new standards and updating the PPR within 60 days. The new standards are released in September and March of each year.
- Development and implementation of action plans to ensure compliance with standard, including development of policies and procedures and education/training
- Monitoring of improvement activities
- Ensuring that finalized projects are communicated effectively to the organization
C. The Quality Director will be responsible for overseeing compliance with the Joint Commission standards.

D. Results of the Periodic Performance Review will be presented to the Board PI Committee on an annual basis.
APPENDIX C

PROTOCOL FOR
SENTINEL EVENT
AND NEAR MISS
Protocol for Sentinel Event and Near Miss Review

I. **Definition of Sentinel Event.** An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

A. Events that are subject to review under the JCAHO’s sentinel event policy include:

1. An event which has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition
   a) Major permanent loss of function is defined as sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change
   b) When “major permanent loss of function” cannot be immediately determined, applicability of the policy is not established until either the patient is discharged with continued major loss of function, or two weeks have elapsed with persistent major loss of function, whichever occurs first
   c) A distinction is made between an adverse outcome that is related to the natural course of the patient’s illness or underlying condition (not reviewable under the policy) and a death or major permanent loss of function that is associated with the treatment, or lack of treatment, of that condition (reviewable)

2. Examples of sentinel events in the community health center setting include:
   a) Medication errors resulting in death or permanent loss of function
   b) Delay in treatment resulting in death or permanent loss of function
c) Procedure performed on the wrong patient or wrong body part

B. Identification of Sentinel Event

1. The event is immediately reported to the Clinic Director/Manager and an event report completed

2. The following individuals will be immediately notified of the event:
   - Executive Director
   - Medical Director/Dental Director
   - Operations Director
   - Quality Director

3. As soon as possible after the event, a meeting will be held with the above participants to review the facts and to make a determination if a sentinel event has occurred.

4. If a sentinel event has occurred, a root cause analysis will be conducted by the appropriate PI committee and the event will be recorded on the sentinel event log.

5. If the event is not a sentinel event, the Administrative Team will determine further disposition based on the facts. The event report may be updated and closed. A root cause analysis may be completed.
   a) The chart review data may be filed in the sentinel event log and the process considered complete and/or
   b) Intensive analysis may occur through the appropriate health center unit/program as part of the PI process

C. Conducting a Root Cause Analysis

1. Definition. A root cause analysis is a process for identifying the basic or causal factors that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event. An acceptable root cause analysis includes the following characteristics:
   - The analysis focuses primarily on systems and processes, not individual performance
• The analysis progresses from special causes in clinical processes to common causes in organizational processes

• The analysis repeatedly digs deeper by asking "Why?"; then, when answered, "Why?" again, and so on. May use other root cause tools specific to the nature of the occurrence.

• The analysis identifies changes which could be made in systems and processes that would reduce the risk of such events occurring in the future

• The analysis is thorough and credible

2. To meet Joint Commission requirements, the root cause will be completed within 45 calendar days of the event or 45 days from the date that we became aware of the event.

3. The Quality Director, in conjunction with the Medical Director, will complete a flowchart of the event.

4. The committee will be responsible for completing a thorough and credible root cause analysis utilizing the Joint Commission format and matrix, process flowchart, pertinent policies and procedures, and any other information deemed appropriate.

A thorough analysis includes:

• A determination of the human and other factors most directly associated with the sentinel event, and the process(es) and systems related to its occurrence.

• Analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk.

• Inquiry into all areas appropriate to the specific type of event as described in the current edition of “Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events”

• Identification of risk points and their potential contributions to this type of event

• A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist

Disclaimer about this document: http://bphc.hrsa.gov/technicalassistance/resourcecenter/disclaimers.html
A credible analysis includes:

• Include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review
• Be internally consistent, i.e. not contradict itself or leave obvious questions unanswered
• Provide an explanation for all findings of “not applicable” or “no problem” and
• Include any consideration of any relevant literature

D. Risk Reduction Strategy and Action Plan

1. An acceptable action plan will be created by the committee utilizing Joint Commission’s format
2. The plan should identify who is responsible for implementation, when the action will be implemented, and how the effectiveness of the actions will be evaluated for every finding that requires action
3. In the event that an action is not taken, the plan should provide a rationale for not undertaking such action

E. Communication of Event

1. The root cause analysis will be filed in the Administrative Office as part of the peer review/sentinel event documentation. Copies will not be distributed.
2. The Risk Reduction Strategy and Action Plan will be provided to those participating in its development and those responsible for implementing action.
3. The Risk Reduction Strategy and Action Plan will be reported to the Board PI Committee and the PI Committee at least on a semi-annual basis until all items have been completed.

F. Joint Commission Notification

1. If the Joint Commission becomes aware of a sentinel event occurring at the health center the health center has 45 days from the date of Joint Commission inquiry to:

a) Submit or otherwise make available an acceptable root cause analysis or action plan, OR

b) Provide for Joint Commission evaluation of the health center's response to the sentinel event

2. The decision to make information available to Joint Commission will be made by the Executive Director in conjunction with legal counsel.

II. Definition of a Near Miss. Any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. Near misses are viewed by the organization as opportunities to improve. All reported near misses will be reviewed and analyzed in the appropriate PI Committee. A root cause analysis may or may not be completed dependent upon the facts of the event.

A. A near miss is to be reported through the event reporting system.

1. The Quality Director, in conjunction with the Medical Director, will review all near misses and assign to the appropriate committee for analysis.

2. Actions that may be taken include:

a) A chart review and timeline of the event may be completed.

b) Other staff who was involved with the event may be contacted to gather facts and provide additional information.

c) Intensive analysis or a root cause analysis may occur as part of the PI process.
# Root Cause Analysis and Action Plan for Near Miss

<table>
<thead>
<tr>
<th>Questions</th>
<th>Findings</th>
<th>Root Cause</th>
<th>Ask Why</th>
<th>Take Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the details of the event (brief description)</td>
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<td>When did the event occur? (Date, day of week, time)</td>
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<td>What area/service was impacted?</td>
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<tr>
<td>What are the steps in the process, as designed? (A flow diagram may be helpful here)</td>
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<td>What steps were involved in (contributed to) the event?</td>
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<td>What human factors were relevant to the outcome?</td>
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<tr>
<td>How did the equipment performance affect the outcome?</td>
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</table>

<table>
<thead>
<tr>
<th>Questions</th>
<th>Findings</th>
<th>Root Cause</th>
<th>Ask Why</th>
<th>Take Action</th>
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</thead>
<tbody>
<tr>
<td>What factors directly affected the outcome?</td>
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<tr>
<td>Are the uncontrollable external factors truly beyond the organization’s control?</td>
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<td>Are there any other factors that have directly influenced this outcome?</td>
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<td>What other areas or services are impacted?</td>
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<td><strong>Human Resources</strong></td>
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<tr>
<td>To what degree are staff properly qualified and currently competent for their responsibilities?</td>
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<td>How did actual staffing compare with ideal levels?</td>
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<tr>
<td><strong>Human Resources</strong></td>
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<tr>
<td>What are the plans for dealing with contingencies that would tend to reduce effective staffing levels</td>
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<td>To what degree is staff performance in the operant process(es) addressed?</td>
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<table>
<thead>
<tr>
<th>Questions</th>
<th>Findings</th>
<th>Root Cause</th>
<th>Ask Why</th>
<th>Take Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>How can orientation and in-service training be improved</td>
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<tr>
<td><strong>Information Management</strong></td>
<td>To what degree is all necessary information available when needed?</td>
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<td>Accurate?</td>
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<td>Complete?</td>
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<td>To what degree is communication among participants adequate?</td>
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<tr>
<td><strong>Environmental Management</strong></td>
<td>To what degree was the physical environment appropriate for the processes being carried out?</td>
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<td></td>
<td>What systems are in place to identify environmental risks?</td>
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<td></td>
<td>What emergency and failure-mode responses have been planned and tested?</td>
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<td>To what degree is the culture conducive to risk identification and reduction?</td>
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<tr>
<td>What are the</td>
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<tr>
<td>Questions</td>
<td>Findings</td>
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<tr>
<td>---------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
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<tr>
<td>barriers to communication of potential risk factors?</td>
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<td>To what degree is the prevention of adverse outcomes communicated as a high priority? How?</td>
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<td>What can be done to protect against the effects of these uncontrollable factors?</td>
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</table>

This template is provided as an aid in organizing the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the analysis. However, all possibilities and questions should be fully considered.

As an aid to avoiding “loose ends,” the three columns on the right are provided to be checked off for later reference:

- “Root cause” should be answered “yes” or “no” for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a “Why?” question. Each finding that is root cause should be considered for an action and addressed in the action plan.

- “Ask ‘Why?’” should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn’t occur when it should have) – in other words, to drill down further. Each item checked in this column should be addressed later in the analysis with a “Why?” question. It is expected that any significant findings that are not causes will have check marks in this column. Also, items that are identified as root causes will often be checked in this column, since many root causes themselves have “roots”.

- “Take Action?” should be checked for any finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item on page 3 in the “Take Action” column for each of the Findings that requires an action.

Primary Health Care, Inc.
Root Cause Analysis
Action Plan for Near Miss Event

<table>
<thead>
<tr>
<th>Risk Reduction Strategies</th>
<th>Measures of Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>For each of the findings identified in the analysis as needing an action, indicate the planned action, expected implementation date, and associated measure of effectiveness, OR…</td>
<td>Measure:</td>
</tr>
<tr>
<td>If, after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time.</td>
<td>Measure:</td>
</tr>
<tr>
<td>Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.</td>
<td>Measure:</td>
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<tr>
<td>Consider whether pilot testing of a planned improvement should be conducted.</td>
<td>Measure:</td>
</tr>
<tr>
<td>Improvements to reduce risk should ultimately be implemented in all areas where applicable, not just where the event occurred. Identify where the improvement will be implemented.</td>
<td>Measure:</td>
</tr>
</tbody>
</table>

Action Item #1: Measure: |
Action Item #2: Measure: |
Action Item #3: Measure: |
Action Item #4: Measure: |
Action Item #5: Measure: |

Cite any books or journal articles that were considered in developing this analysis and action plan:

FIGURE 1

### Schedule of Performance Improvement Reports

#### Performance Improvement Committee

<table>
<thead>
<tr>
<th>MONTH</th>
<th>YEAR</th>
<th>STAFF PI ACTIVITY</th>
<th>PI/AUXILIARY REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>May</td>
<td>2008</td>
<td>Clinical PI Operations Meeting</td>
<td>Clinical Core Measures from the Strategic Dashboard</td>
</tr>
<tr>
<td>June</td>
<td>2008</td>
<td>Program PI Operations Meeting</td>
<td>Program Core Measures from the Strategic Dashboard</td>
</tr>
</tbody>
</table>
| Jul   | 2008 | All PI Operations Team Meeting         | **Safety/Infection Control**  
Safety, IC Performance & Quality Measures  
Semi-annual Safety Environmental Rounds Tour Report  
SRM Event Reports  
Problem Logs (if any)  
Emergency Mgmt Evaluation (if any)  
Product Recall (if any)  
Sentinel Event Alert/Update (if any)  
**Pharmacy and Therapeutics**  
Medication Errors  
Adverse Drug Reactions  
Med System Validation for Sites  
Pharmaceutical Recalls  
Medication Management Policy Approval  
Formulary Additions and Deletions (340b, Non-340b, and PAP)  
**Patient Satisfaction & Complaints**  
**Financial Measures**  
| Aug   | 2008 | Clinical PI Operations Meeting         | Clinical Core Measures from the Strategic Dashboard |
| Sept  | 2008 | Program PI Operations Meeting          | Program Core Measures from the Strategic Dashboard |
| Oct   | 2008 | All PI Operations Team Meeting         | **SAFETY/IC**  
Safety/IC Performance Measures  
Semi-annual Safety Environmental Rounds Tour Report  
Patient Satisfaction & Complaints  
SRM Event Reports  
Problem Logs (if any)  
Emergency Mgmt Evaluation (if any)  
Product Recall (if any)  
Sentinel Event Alert/Update (if any)  
**P&T**  
Medication Errors  
Adverse Drug Reactions  
Med System Validation for Sites  
Pharmaceutical Recalls  
Formulary Additions and Deletions (340b, Non-340b, and PAP)  

<table>
<thead>
<tr>
<th>MONTH</th>
<th>YEAR</th>
<th>STAFF PI ACTIVITY</th>
<th>PI/AUXILIARY REPORTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patient Satisfaction &amp; Complaints</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Financial Measures</td>
</tr>
<tr>
<td>Nov</td>
<td>2008</td>
<td>Clinical PI Operations Meeting</td>
<td>Clinical Core Measures from the Strategic Dashboard</td>
</tr>
<tr>
<td>Dec</td>
<td>2008</td>
<td>Program PI Operations Meeting</td>
<td>Program Core Measures from the Strategic Dashboard</td>
</tr>
<tr>
<td>Jan</td>
<td>2009</td>
<td>All PI Operations Team Meeting</td>
<td>Safety/IC</td>
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<td></td>
<td>Safety/IC Performance Measures</td>
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<td></td>
<td>Sentinel Event Alert/Update (if any)</td>
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<td></td>
<td></td>
<td></td>
<td>IC Annual Program Review:</td>
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<tr>
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<td></td>
<td>Annual IC Training</td>
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<td>Annual Eval of Safety Devices</td>
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<td>Annual Review of Exposure Control/IC Plans</td>
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<td>Annual TB Screening of Employees - January</td>
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<td>Annual Hep B Vaccination of Employees – January</td>
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<td>Safety Annual Program Review:</td>
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<td>Annual Safety Program Eval</td>
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<td>Annual Hazard Vulnerability/Risk Assessment</td>
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<td>Annual Safety Training</td>
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<td>Annual Evaluation of Safety Program (includes review of annual fire drill requirements/evaluation)</td>
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<td>Patient Satisfaction &amp; Complaints</td>
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<td>P&amp;T</td>
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<td>Medication Errors</td>
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<td>Adverse Drug Reactions</td>
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<td>Med System Validation for Sites</td>
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