Frequently Asked Questions About the National Nursing Home Quality Care Collaborative (NNHQCC) Composite Measure
July 2014

Q1: What is the NNHQCC Composite Measure?

A: The NNHQCC composite measure is a tool that can be used to help monitor NNHQCC progress. Nursing homes participating in the NNHQCC focus on processes that improve their systems and measure individual tests of change. Specifically, they look at their Plan-Do-Study-Act (PDSA) improvement cycle results, clinical outcomes measures and composite scores. The composite measure is not intended to replace or supersede existing local or federal initiatives, including the 5-star rating system, but is offered as another way to look at quality from a systems perspective.

Q2: Which quality measures are included in the composite measure?

A: The composite is comprised of 13 NQF-endorsed, publically reported, long-stay quality measures that represent larger systems within the long term care setting:

1. Percent of residents with one or more falls with major injury
2. Percent of residents with a urinary tract infection (UTI)
3. Percent of residents who self-report moderate to severe pain
4. Percent of high-risk residents with pressure ulcer
5. Percent of low-risk residents with loss of bowels or bladder
6. Percent of residents with catheter inserted or left in bladder
7. Percent of residents physically restrained
8. Percent of residents whose need for help with Activities of Daily Living (ADL) has increased
9. Percent of residents who lose too much weight
10. Percent of residents who have depressive symptoms
11. Percent of residents who received antipsychotic medications
12. Percent of residents assessed and appropriately given the seasonal influenza vaccine
13. Percent of residents assessed and appropriately given the pneumococcal vaccine

Q3: What is the data source?

A: Facility-level quality measure numerators, denominators and rates derived from the MDS 3.0 are extracted from the Quality Improvement and Evaluation System (QIES) Workbench for rolling six-month time periods on a monthly basis and used to calculate the composite score. There is a two-month delay from the last month of the time period. For example, the January through June time period would be extracted on the first business day after the first weekend in September; the February through July time period would be extracted on the first business day after the first weekend in October; the March through August time period would be extracted on the first business day after the first weekend in November, and so forth.
Q4: How is the composite score calculated?

A: The composite score is calculated based on the “opportunity model” concept. Numerators and denominators are summed across all 13 quality measures to determine the composite numerator and denominator. The composite numerator is then divided by the composite denominator and multiplied by 100 to obtain the composite score. (Please note that before the numerators and denominators can be summed, the direction of the two vaccine measures must be reversed because they are directionally opposite of the others. This can be done by subtracting the vaccine numerator from the vaccine denominator to obtain a “reversed” numerator. This “reversed” numerator is what should be counted in the composite numerator. By keeping all measure directions consistent, the composite score can be interpreted as the lower, the better.)

Q5: Why are there fluctuations in the season influenza vaccine measure rates?

A: Fluctuations in vaccine measure rates, across the six-month time periods, are expected. These are likely attributable to two factors: 1) the time period ends at the beginning or during the flu season, when many residents haven’t yet had the chance to be assessed and appropriately given the vaccine; and 2) the definition of “current” flu season may vary among healthcare providers and across states.

Q6: How is the composite score evaluated?

A: The NNHQCC seeks to rapidly spread the practices of high performing nursing homes with the aim of ensuring that every nursing home resident receives the highest quality of care. Specifically, the NNHQCC strives to instill quality and performance improvement practices, eliminate healthcare acquired conditions, and dramatically improve resident satisfaction through the achievement of a rate of 6 or less.

Q7: How was the goal of “6 or less” established?

A: Prior to the launch of the NNHQCC, nearly 10 percent of the nation’s nursing homes had achieved a composite score of 6 or less. Additionally, the 10 nursing homes identified for “best practices” site visits had an average composite score close to 6, and the national benchmark, using the Achievable Benchmarks of Care (ABC) method, was around 6.

Q8: Will Quality Improvement Network-Quality Improvement Organizations (QIN-QIOs) be able to calculate their state and individual nursing homes scores?

A: QIN-QIOs can calculate their state aggregate and individual nursing home composite scores using the facility-level data files provided by the National Coordinating Center (NCC) and following the method of composite score calculation as described earlier. The files provided by the NCC contain individual measure and composite measure numerators, denominators, and rates for every facility within their state. A second option is to download the individual measure data from CASPER (Certification and Survey Provider Enhanced Reports) and follow the same method for calculating the composite score. However, the two vaccination measures are not reported on CASPER and would have to be excluded from the composite measure if using this data source to calculate state and individual nursing home composite scores. (See Attachment 1 “Information Regarding the Percent of Long-Stay Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine Nursing Home Quality Measure”)

Q9: Some community-based nursing facilities are not Medicare or Medicaid certified. Are they included in the state composite score?

A: Nursing homes without a CMS Certification Number (CCN) cannot be included when calculating a composite score.

Q10: Can nursing homes calculate their own composite scores?

A: Nursing homes can approximate their own composite scores using the publically available data on Nursing Home Compare, although the time frames reported there are different than the rolling six-month time periods used to monitor progress in the Collaborative. Nursing homes could also use CASPER data, although the two vaccination measure are not reported there and would have to be excluded from the composite measure if using this data source to calculate the composite score.

Q11: Can QIN-QIOs share individual nursing home composite scores with corporations or other stakeholders?

A: QIN-QIOs must follow provisions outlined in Part B of Title XI of the Social Security Act (the Act). Sections 1154, 1156, and 1160 provide the basis for the acquisition, protection, and disclosure of information. 42 CFR Part 480 implements the above referenced provisions of the Act. “Confidential information” includes information that explicitly or implicitly identifies an individual patient, practitioner, institution, or reviewer. Practitioner, reviewer and provider confidential information may only be disclosed to the identified practitioner, reviewer or provider, and this would include only information about them. Disclosure to others requires the written consent of the identified practitioner, reviewer or provider. QIN-QIOs should follow their organization’s QIN-QIO contractual confidentiality and disclosure policies.

Q12: Are there significant differences in the composite scores across the nation?

A: Composite scores vary across facilities and states.
Information Regarding the “Percent of Long-Stay Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine” Nursing Home Quality Measure

Background
Seasonal fluctuations have been noted in the “percent of long-stay residents assessed and appropriately given the seasonal influenza vaccine” nursing home quality measure rates for rolling six-month time periods that are updated on a monthly basis (and, to a much lesser extent, also in the “percent of long-stay residents assessed and appropriately given the pneumococcal vaccine” nursing home quality measure rates for rolling six-month time periods which are updated on a monthly basis). The change appears to peak during the May through October time period before returning to normal at the November through April time period. The graph below illustrates the fluctuations. These fluctuations are likely attributable to two factors: 1) the time period ends at the beginning or during the flu season when many residents haven’t yet had the chance to be assessed and appropriately given the vaccine; and 2) the definition of “current” flu season may vary among healthcare providers and across states.

Flu and pneumonia vaccine opportunity rates (percent of residents not yet immunized): Dec. 2011-April 2014

Timing of Vaccination and Assessment
Because the rolling six-month time periods are updated on a monthly basis (dropping the first month and adding the next month at each cycle), time periods that end with a month or two at the beginning or during the flu season are likely to include residents who have not yet been vaccinated for the current season that just started. Since all residents cannot be vaccinated simultaneously on Day 1 of the flu season, the six-month time periods that end on a month or two of the flu season are likely to include more residents who have not had a chance to be vaccinated or assessed. This explains the seasonal peak we consistently observe in the influenza measure rates as depicted in the graph above.

Although the Pneumococcal vaccination is a year-around activity, the subtle fluctuation we also observe for the pneumococcal vaccination during the flu season may be due to the fact that some healthcare providers may tend to intensify pneumococcal vaccination assessment during the flu season as well.
Defining Flu Season
The current MDS 3.0 Resident Assessment Instrument (RAI) Manual indicates that flu season varies annually and geographically, ending “when influenza is no longer active in your geographic area.” For more information, the manual suggests that healthcare providers visit the Centers for Disease Control and Prevention (CDC) website which states that the flu season can occur as early as October and advises them to “begin offering vaccination soon after vaccine becomes available and, if possible, before October.” Additionally, some states have their own definition of flu season that can begin earlier than October. The inconsistency in the timing of the flu season may explain why small changes in the measure rate begin during the six-month time periods before the biggest change in the measure rate during the May through October six-month time period.

What Does This Mean?
• We will likely continue to see fluctuations in the immunization measures that will affect the overall Composite Measure used to assess progress in the National Nursing Home Quality Care Collaborative.
• The immunization measures will remain in the Composite Measure, given the important vaccine benefits to nursing home residents.
• This fluctuation does not necessarily mean that any nursing home is out of compliance with providing timely vaccinations.
• Nursing homes should be encouraged and supported to immunize all residents appropriately in a timely manner.
Scoring Resident ADLs

**INDEPENDENT – SCORE OF ZERO “0” – NO talk, NO touch**

This person is **Independent**. She *never* needs your supervision or assistance. You *never* lay a hand on her. You may ‘set her up’ with a walker next to her bed, or lay out her clothes, but you do not assist her in any way physically or verbally. (Remember that people can be independent in some areas and require assist in others—score each ADL individually and accurately)

**SUPERVISION – SCORE OF ONE “1” – TALK, NO touch**

This is **Supervising**. You never touch the person; you only provide verbal cues and may be there for Stand by Assist. As soon as the assistance moves to the point that you touch the patient, they are not Supervised, but advance to the next level:

**LIMITED ASSISTANCE – SCORE OF TWO “2” – TOUCH, NO Lift**

Now you have touched the person – hands on but you do not bear any weight. This is equivalent to Contact Guard Assist (CGA) with therapy. You may have the transfer belt on, but you are only there for **Guidance**. You *Never lift, push or pull any part of the patient*—in any way. There is absolutely No Weight Bearing. **Only Guidance**. (If you were transferring or ambulating with a belt and the pt went off balance and you needed to pull them back to balance, that would = weight bearing and would not be limited assist.)

*No lifting, only Guidance*
EXTENSIVE ASSISTANCE – SCORE OF THREE “3” – TOUCH WITH LIFT, PUSH, PULL

- Touching the person and: **Weight bearing**
  - Pushing, Pulling or Lifting. Any time you must assume the patient’s weight, this is weight bearing. **Most ‘hands on assist’ is Weight Bearing (Extensive Assist)**
- Pulling up pants while supporting resident = **weight bearing**;
- Boosting to stand = **weight bearing**;
- Lifting a spoon to the mouth = **weight bearing**;
- Applying TED hose while supporting leg = **weight bearing**;
- You complete peri-care after toileting = **weight bearing**;
- Assisting the patient to sit up in bed = **weight bearing**;
- Lifting their legs into bed = **weight bearing**
- Managing Foley or Ostomy = **weight bearing**
- Eating food but nurse does tube feeding = **weight bearing**

Weight bearing = Extensive Assist. It can be minimum or maximum, but any weight bearing is Extensive Assist.

**Any amount of Weight Bearing (pushing, pulling or lifting) = Extensive Assistance.**

TOTAL ASSISTANCE – SCORE OF FOUR “4”

**Total assist** means that the person does **Nothing** for themselves. Only code this when the person does not participate. If they bear weight with their feet, help get themselves dressed or eat part of their meal, do not code them Total Assist (code them Extensive Assist). Total assist means that the task was performed entirely by staff like when someone is in a coma.
QAPI Step 7

Develop a Strategy for Collecting & Using Data

Effective use of data will help ensure that decisions are made based on fact, and not on an assumption of the truth. Just as a physician needs data about a patient to diagnose a condition, QAPI teams and PIP teams will need data to ensure they are targeting the right areas.

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<thead>
<tr>
<th>Action Step</th>
<th>Who Is Responsible?</th>
<th>Date Completed</th>
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<tbody>
<tr>
<td>Determine what data to monitor routinely.</td>
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<td>Set targets for performance in the areas you are monitoring.</td>
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<tr>
<td>Identify benchmarks for performance.</td>
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<td>Develop a data collection plan, including who will collect which data, who will review it, the frequency of collection and reporting, etc.</td>
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Questions for Team Discussion

1. What data do our facility routinely monitor? How are these data displayed and used?

2. What benchmarks will we use when assessing our performance?

3. How can we make better use of the data we have? Do we track and trend our progress over time?

4. How are data shared with others in the organization? Staff? Residents/families? The Board or corporate office?

Surpassing the Hurdles

1. What barriers do you anticipate with these action steps?

2. What additional information does your team need?

3. What additional resources would be helpful?

4. What structures can you create to help ensure your success with this step?
QAPI Step 7

Develop a Strategy for Collecting & Using Data

Suggestions for Implementing Step 7

- Areas to consider for data monitoring include clinical care areas, medications, resident/family complaints, hospitalizations, state survey results and business and administrative processes.
- When setting targets, consider the long-term as well as short-term goals.
- When identifying benchmarks, you can look at your performance compared to nursing homes in your state and nationally using Nursing Home Compare. Generally, because every facility is unique, the most important benchmarks are often based on your own performance.
QAPI Step 8

Identify Your Gaps & Opportunities

Whether you are reviewing data from the Minimum Data Set (MDS) or quality measure reports, data from satisfaction surveys or consultant reports, or any other source, be sure you are identifying any trends in the data you review. Use this time to observe for any areas where processes are breaking down.

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<tr>
<td>Review information to determine if gaps or patterns exist in your systems of care, or if opportunities exist to make improvements.</td>
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<td>Discuss any emerging themes with residents and caregivers.</td>
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<td>Notice what things your organization is doing well in identified areas.</td>
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<td>Set priorities for improvement.</td>
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Questions for Team Discussion

1. When reviewing your data, what stands out?

2. How strong is your organizational capacity for assessing facility systems (e.g., policies, protocols, actual care delivery)?

3. What are some areas of strength and weakness?

4. What opportunities do you see?

Surpassing the Hurdles

1. What barriers do you anticipate with these action steps?

2. What additional information does your team need?

3. What additional resources would be helpful?

4. What structures can you create to help ensure your success with this step?
Identify Your Gaps & Opportunities

Suggestions for Implementing Step 8

- Measure important indicators of care that are relevant and meaningful to the residents that you serve.
- Guide and empower staff to solve problems. For example, leaders should respond to problems that are raised—not by proposing a solution, but by asking the team to investigate and determine what they believe would work best.
- Hold short stand-up meetings with managers and staff for each shift to identify concerns, resources, needs, etc.
- Establish the nursing home as a learning organization in which all staff identifies areas for improvements.
- Regularly discuss processes and systems to identify areas for improvement—in meetings as well as everyday interactions.
- Empower residents to get involved in identifying areas of improvement.
QAPI Step 9

Prioritize Opportunities & Charter PIPs

Be sure you are choosing areas that you consider important (e.g., areas of high risk, frequent occurrence, or areas that are known problems). Remember that not all identified problems require PIPs, but for those that do, the projects need to be structured, or “chartered.”

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<tr>
<td>Prioritize opportunities for more intensive improvement work.</td>
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<td>Consider which problems need the focus of a PIP.</td>
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<td>Charter PIP teams, by selecting a leader and defining the mission.</td>
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<td>PIP teams should develop timelines and indicate budget needs.</td>
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<tr>
<td>PIP teams should use the Goal Setting Worksheet to establish appropriate goals.</td>
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Questions for Team Discussion

1. How will organizational priorities be determined?

2. Who will be responsible for monitoring the overall progress of our PIPs?

3. What education is needed for PIP teams?

Surpassing the Hurdles

1. What barriers do you anticipate with these action steps?

2. What additional information does your team need?

3. What additional resources would be helpful?

4. What structures can you create to help ensure your success with this step?
QAPI Step 9

Prioritize Opportunities & Charter PIPs

Suggestions for Implementing Step 9

- Get everyone involved in setting goals—residents, staff, family members, and Board members.
- If practices are not making sense or are frustrating to staff, residents or family, do not settle for “this is just the way it has to be,” challenge and sort out what you have control over, and look for ways to address improvements.
Quality Assurance and Performance Improvement

Under requirements of the Affordable Care Act of 2010, all skilled nursing facilities/nursing facilities will be required to establish and implement a Quality Assurance and Performance Improvement (QAPI) initiative, including those that are part of a multi-unit chain of facilities.

Quality Assessment and Assurance (QAA) Committee

Currently each nursing facility is required to maintain a QAA Committee that includes minimally the Director of Nursing, a physician designated by the facility and three other members of the facility’s staff.

New: The Infection Control and Prevention Officer will now participate in the QAA Committee. The Committee membership may, at the facility’s discretion, also includes additional individuals, for example some facilities may wish to include a pharmacist to coordinate QAPI activities related to reducing the use of psychotropic medications. The QAA Committee may also benefit from including individuals such as a resident council president, or directors of social services or activities. The committee will review and analyze data collected as part of the QAPI program, including an annual performance improvement project (PIPs) that focuses on high risk/problem prone area, and data from pharmacists resulting from monthly drug regimen reviews and reports.

“We propose to clarify that quality of care and quality of life are overarching principles in the delivery of care to residents of nursing homes.”

Quality Assurance & Performance Improvement Activities

New: The QAA Committee will now be required to use QAPI techniques to monitor and evaluate the performance of their facility. A facility will be required to develop, implement, and maintain an effective, comprehensive, data-driven QAPI plan that focuses on systems of care, outcomes and services for residents and staff. The QAPI plan would be designed to monitor and evaluate performance of all services and programs of the facility, including services provided under contract or arrangement.

New: Each facility will be required to design and incorporate quality improvement into their facility routine. Each facility’s governing body will ensure that the QAPI plan is defined, implemented and maintained to address identified priorities.

New: Nursing facilities may already be conducting quality assurance activities. A facility will need to submit a QAPI plan that includes a description of how it will coordinate implementation of QAPI with current quality assurance activities being conducted.

New: A facility will be required to maintain documentation and demonstrate evidence of the facility’s QAPI Plan. Each facility must present, and have available upon request, their ongoing QAPI Plan to the State Agency Surveyor, as well as to a federal surveyor or CMS at the first annual recertification survey that occurs at least 1 year after the effective date of these regulations, and at each annual recertification survey. The State Agency will consider the QAPI plan in making its certification recommendations and providing evidence to CMS for compliance determination.
What does this mean?

As a part of the QAPI process each facility will:

- Create a system to obtain and use feedback from direct care workers, staff, residents, resident representatives and family members to identify opportunities for improvement.
- Identify, collect, and use data from all departments to identify high risk or problem-prone areas.
- Determine a method for developing, monitoring, and evaluating performance indicators.
- Identify a process for identifying, reporting, analyzing and preventing adverse events or near misses. This would include methods by which a facility would obtain information on adverse events and potential adverse events from residents, family and direct care/direct access staff, and how the facility will address and investigate the adverse event or potential adverse event and provide feedback to those same individuals.

The QAPI plan, when implemented, will be required to address all systems of care and management practices – and will always include clinical care, quality of life and resident choice.

**QAPI Focus**

The QAPI plan will establish priorities that focus on:

- Patient safety
- Coordination of care
- Autonomy
- Choice
- High risk, high volume, and/or problem prone areas

**QAPI Requirements**

Each QAPI plan must:

- Be sustained during leadership or staff transitions.
- Guarantee adequate resources – ensuring enough staff time, equipment and training is provided.
- Identify and prioritize problems and opportunities based on performance indicator data, resident and staff input, services provided to residents, corrective actions, safety, and quality expectations.
- Track medical errors and adverse resident events, analyze their causes, and implement preventative actions that include feedback and lessons learned.
- Include mandatory training for staff on QAPI.
- Provide access to QAPI systems and reports that demonstrates a facility is in compliance.

**TIME COMMITMENT**

CMS time estimates for QAPI:

- Initial setup time of 56 hours to develop and document a QAPI program
  - 30 hours: administrator or coordinator develop overall QAPI program
  - 20 hours: 10 hours director of nursing and 10 hours registered nurse review and provide input on clinical services
  - 4 hours: physician review and provide medical input
  - 2 hours: office assistant to prepare and distribute draft and final plans
- 20 hours annually: ongoing collecting and analyzing data for QAPI activities

**There is help---**

- The [CMS Website](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapiresources.html) provides links for Guides to Quality as well as several helpful websites for accessing QAPI tools.
- A [Process Tool Framework](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/ProcessToolFramework.pdf) has been created to crosswalk each CMS Process Tool to the QAPI Five Elements.
- The [QIO Network](http://www.qioprogram.org/) provides technical assistance and works with providers to focus on quality improvement measures, such as decreasing healthcare associated conditions, and engaging with providers participating in the National Nursing Home Quality Care Collaborative.
- The [Advancing Excellence in America’s Nursing Homes](http://www.nhqualitycampaign.org) Campaign offers free tools and resources to support evidence-based quality improvement programs on nine goals.

This material was prepared by Telligen, the Quality Innovation Network National Coordinating Center, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.
**Directions:** This tool will assist in choosing which potential areas for improvement are the highest priority based on the needs of the residents and the organization. Follow this systematic assessment process below to identify potential areas for PIPs. This process will consider such factors as high-risk, high-volume, or problem-prone areas that affect health outcomes and quality of care. This tool is intended to be completed and used by the QAPI team that determines which areas to select for PIPs. Begin by listing potential areas for improvement in the left-hand column. Then score each area in the following columns based on a rating system of 1 to 5 as defined below:

<table>
<thead>
<tr>
<th>1 = very low</th>
<th>2 = low</th>
<th>3 = medium</th>
<th>4 = high</th>
<th>5 = very high</th>
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Rating is subjective and is meant to be a guide and to stimulate discussion. Finally, add the scores across the row and tally in the final column. Potential improvement areas with a higher score indicate a higher priority.

<table>
<thead>
<tr>
<th>POTENTIAL AREAS FOR IMPROVEMENT</th>
<th>PREVALENCE</th>
<th>RISK</th>
<th>COST</th>
<th>RELEVANCE</th>
<th>RESPONSIVENESS</th>
<th>FEASIBILITY</th>
<th>CONTINUITY</th>
<th>TOTAL SCORE TALLY</th>
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<tr>
<td>Consider areas identified through:</td>
<td>Dashboard(s) Feedback from staff, families, residents, other Incidents, near misses, unsafe conditions Survey deficiencies</td>
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Disclaimer: Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
Additional factors to take into account:

1. What existing standards or guidelines are available to provide direction for this initiative?
2. What measures can be used to monitor progress?
3. Is the topic publicly reported on Nursing Home Compare and/or is it a goal of the Advancing Excellence in America’s Nursing Homes campaign?
4. Which type of changes primarily will be involved (i.e., system changes, environmental changes, staffing changes)?
5. Which staff will be most affected by the initiative? What training needs will this initiative present?
6. Is there an identified champion(s) for this initiative?
Directions: Use this check list to ensure you have covered important steps in launching your performance improvement project. This tool is intended to be used by the person asked to lead a PIP or any project where a team has been formed. Use this check list to make sure you have everything you need in place when you start a project. Ensuring you have these steps in place can help you save time and confusion down the road.

Project Name:

Project Stakeholders and Team Members

☐ The team has received a project charter that has been approved by the leadership.
☐ The project team has been assembled and roles and responsibilities have been assigned.
☐ The project charter is understood and accepted by all project team members.
☐ The project team understands how the project fits with the overall goals of the organization.
☐ Each project team member understands how his/her assignment fits into the overall project.
☐ The project and its goals have been communicated to stakeholders outside of the project team, as needed (e.g., residents and families, staff, board of directors, owners).

Project Resources

☐ Financial support for the project has been obtained.
☐ A project budget has been established.
☐ Staff time to work on the project has been allocated.
☐ Material resources required for the project have been identified and secured.

Project Process

☐ A detailed timeline and work plan have been created.
☐ Training needs have been identified and training has been conducted.
☐ A schedule for regular project team meetings has been set.
☐ Indicators/measures have been established to monitor project goals (see Goal Setting Worksheet).
☐ The format and frequency for documenting project status has been defined.
☐ The format, frequency, and audiences for communicating project status has been defined.
☐ A process to identify issues that come up during this project is established (e.g., unintended consequences, new opportunities for process changes, surprises).
☐ The location for storing all project documents, and processes for file naming conventions and version control has been established.
☐ The time for project kickoff has been identified and any related activity required (e.g., announcement, meeting, event) has been planned.
**Performance Improvement Project (PIP) Inventory**

*Directions*: Use this template for high level tracking of all PIPs occurring within your organization. This document may be particularly useful for leadership, surveyors, or others responsible for overall monitoring of the program. Consider updating the status column on a regular basis; e.g., quarterly. This may be helpful to bring to the QAPI team meetings, to review all PIPs that the organization has currently underway, to identify if the PIPs are moving along, if any have stalled, etc.

**Date(s) of Review: ____________________________**

<table>
<thead>
<tr>
<th>Project Name</th>
<th>Start Date</th>
<th>Current Phase</th>
<th>Purpose</th>
<th>Change(s) Initiated</th>
<th>Indicators/Measures</th>
<th>Status</th>
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Disclaimer: Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
Directions: Use this Plan-Do-Study-Act (PDSA) tool to plan and document your progress with tests of change conducted as part of chartered performance improvement projects (PIPs). While the charter will have clearly established the goals, scope, timing, milestones, and team roles and responsibilities for a project, the PIP team asked to carry out the project will need to determine how to complete the work. This tool should be completed by the project leader/manager/coordinator with review and input by the project team. Answer the first two questions below for your PIP. Then as you plan to test changes to meet your aim, answer question 3 below and plan, conduct, and document your PDSA cycles. Remember that a PIP will usually involve multiple PDSA cycles in order to achieve your aim. Use as many forms as you need to track your PDSA cycles.

Model for Improvement: Three questions for improvement

1. What are we trying to accomplish (aim)?
   State your aim (review your PIP charter – and include your bold aim that will improve resident health outcomes and quality of care)

2. How will we know that change is an improvement (measures)?
   Describe the measureable outcome(s) you want to see

3. What change can we make that will result in an improvement?

   Define the processes currently in place; use process mapping or flow charting

   Identify opportunities for improvement that exist (look for causes of problems that have occurred – see Guidance for Performing Root Cause Analysis with Performance Improvement Projects; or identify potential problems before they occur – see Guidance for Performing Failure Mode Effects Analysis with Performance Improvement Projects) (see root cause analysis tool):
   - Points where breakdowns occur
   - “Work-a-rounds” that have been developed
   - Variation that occurs
   - Duplicate or unnecessary steps

   Decide what you will change in the process; determine your intervention based on your analysis
   - Identify better ways to do things that address the root causes of the problem
   - Learn what has worked at other organizations (copy)
   - Review the best available evidence for what works (literature, studies, experts, guidelines)
   - Remember that solution doesn’t have to be perfect the first time
<table>
<thead>
<tr>
<th>Plan</th>
<th>List your action steps along with person(s) responsible and time line.</th>
</tr>
</thead>
<tbody>
<tr>
<td>What changes are you testing with the PDSA cycle(s)?&lt;br&gt;What do you predict will happen and why?&lt;br&gt;Who will be involved in this PDSA? (e.g., one staff member or resident, one shift?). Whenever feasible, it will be helpful to involve direct care staff.&lt;br&gt;Plan a small test of change.&lt;br&gt;How long will the change take to implement?&lt;br&gt;What resources will they need?&lt;br&gt;What data need to be collected?</td>
<td></td>
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<tr>
<td>Do</td>
<td>Describe what actually happened when you ran the test.</td>
</tr>
<tr>
<td>Carry out the test on a small scale.&lt;br&gt;Document observations, including any problems and unexpected findings.&lt;br&gt;Collect data you identified as needed during the “plan” stage.</td>
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<td>Study</td>
<td>Act</td>
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<tr>
<td>Study and analyze the data. Determine if the change resulted in the expected outcome. Were there implementation lessons? Summarize what was learned. Look for: unintended consequences, surprises, successes, failures.</td>
<td>Describe what modifications to the plan will be made for the next cycle from what you learned.</td>
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<tr>
<td>Describe the measured results and how they compared to the predictions.</td>
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</table>

**Disclaimer:** Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
Overview: RCA is a structured facilitated team process to identify root causes of an event that resulted in an undesired outcome and develop corrective actions. The RCA process provides you with a way to identify breakdowns in processes and systems that contributed to the event and how to prevent future events. The purpose of an RCA is to find out what happened, why it happened, and determine what changes need to be made. It can be an early step in a PIP, helping to identify what needs to be changed to improve performance. Once you have identified what changes need to be made, the steps you will follow are those you would use in any type of PIP. Note there are a number of tools you can use to perform RCA, described below.

Directions: Use this guide to walk through a Root Cause Analysis (RCA) to investigate events in your facility (e.g., adverse event, incident, near miss, complaint). Facilities accredited by the Joint Commission or in states with regulations governing completion of RCAs should refer to those requirements to be sure all necessary steps are followed.

Below is a quick overview of the steps a PIP team might use to conduct RCA.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Identify the event to be investigated and gather preliminary information</td>
<td>Events and issues can come from many sources (e.g., incident report, risk management referral, resident or family complaint, health department citation). The facility should have a process for selecting events that will undergo an RCA.</td>
</tr>
<tr>
<td>2. Charter and select team facilitator and team members</td>
<td>Leadership should provide a project charter to launch the team. The facilitator is appointed by leadership. Team members are people with personal knowledge of the processes and systems involved in the event to be investigated.</td>
</tr>
<tr>
<td>3. Describe what happened</td>
<td>Collect and organize the facts surrounding the event to understand what happened.</td>
</tr>
<tr>
<td>4. Identify the contributing factors</td>
<td>The situations, circumstances or conditions that increased the likelihood of the event are identified.</td>
</tr>
<tr>
<td>5. Identify the root causes</td>
<td>A thorough analysis of contributing factors leads to identification of the underlying process and system issues (root causes) of the event.</td>
</tr>
<tr>
<td>6. Design and implement changes to eliminate the root causes</td>
<td>The team determines how best to change processes and systems to reduce the likelihood of another similar event.</td>
</tr>
<tr>
<td>7. Measure the success of changes</td>
<td>Like all improvement projects, the success of improvement actions is evaluated.</td>
</tr>
</tbody>
</table>

Steps two through six should be completed as quickly as possible. For facilities accredited by the Joint Commission, these steps must be completed within 45 days of occurrence of the event.
**Step 1: Select the event to be investigated and gather preliminary information**

Events that may be investigated using the RCA process can be identified from many sources (e.g., incident report, risk management referral, staff, resident, or family feedback, health department citation). High priority should be given to events that resulted in significant resident harm or death and other events the facility is required by regulation to investigate. Also consider doing an RCA for “near miss” or “close call” events that could have resulted in harm to the resident, but did not, either by chance or timely intervention. The latter types of events represent high risk situations that could, in the future, cause a resident to be harmed.

Once an event is selected for a Performance Improvement Project (PIP) involving RCA, someone involved in the facility QAPI program can begin gathering preliminary information, including the incident report and any documentation from the preliminary investigation, for later discussion by the team. This may include interviews with those involved including the resident or family members, collection of pertinent documentation or photographs, review of relevant policies and procedures, quarantine of defective equipment, etc. This preliminary information is also useful for deciding which individuals should be invited to serve as members of the team as described in Step 2.

✓ **Helpful Tips:**
  - Involve facility leaders in the prioritization and decision to proceed with an RCA. There will be greater cooperation in completing RCAs when the process is viewed as leadership-driven.
  - Be sure to start with a problem and not the solution. It is tempting to assume we know what will fix the problem before we’ve thoroughly examined it. Assumptions are often wrong and may hinder complete analysis of the underlying causes.
  - Don’t define the problem as a need for something. The problem statement should objectively state what went wrong, not why, or how. An example of an effective problem statement is, “Resident X continued to receive a medication one week after the order was given for discontinuation.” A good problem statement will facilitate a more thorough examination of the problem.
  - If the event represents a liability concern or questionable practices by an employee, the leadership team can initiate a risk management review or an employee performance review to start simultaneous with, but separate, from the RCA process. The RCA process should focus on systems rather than individual performance.

**Step 2: Charter and select team facilitator and team members**

Next, leadership designates a facilitator for the PIP team, and works with the facilitator to create a charter that will help guide the team in managing the scope of the project and making changes that are ultimately linked to the root causes identified in the RCA process. Together, leadership and the facilitator select staff to participate on the PIP team.
As managers and supervisors gain experience in doing RCAs, more people in the facility can be trained to serve as team facilitators. The facilitator is responsible for assembling and managing the team, guiding the analysis, documenting findings and reporting to the appropriate persons.

The number of team members depends on the scope of the investigation. Individuals selected to serve as team members must be familiar with the processes and systems associated with the event. People who have personal knowledge of what actually happened should be included as team members or given an opportunity to contribute to the investigation through interviews.

**Helpful Tips:**

- Team members should be selected for their ability to discuss and review what happened during the event in an objective and unbiased manner. In some situations, staff members personally involved in the event are the best people to serve as team members. In other situations, staff members not personally involved in the event are the best people to serve as team members with the people personally involved asked to share their experience during interviews. This may be appropriate if the people directly involved in the event are dealing with emotions and are not able to be objective. However, if this is the case, it is a good idea to provide those staff persons directly involved with counseling and support so that they are able to participate in the RCA process. Participating in the RCA process and hearing other’s objective viewpoints can help them to deal with the situation in a positive manner.

- Keep the number of management or supervisory level individuals on the team to a minimum. Staff members may be inhibited from speaking up or being completely candid during discussions about what happened if their direct supervisor is in the room. If this is not possible, the facilitator should explain the need for members to be free to discuss the process honestly, as it is actually carried out in the facility.

- Make it clear to everyone involved that the RCA process is confidential. This reassurance helps people feel safer discussing the process and system breakdowns that may have caused an inadvertent mistake.

**Step 3: Describe what happened**

At the first meeting of the team, a time line of the event under review is created. The preliminary information gathered in step 1 is shared with the team and other details about the event are elicited from team members. If the people personally involved in the event are not part of the team, their comments about what happened are shared with team members. All of this information is used to create a time line of the event – the sequence of steps leading up to the harmful event.

Below is a time line for a situation involving a resident that suffered a serious injury during his transfer from a wheelchair back to his bed. This tall and larger man (300-pound) was placed in a Hoyer lift and elevated into the air above his wheelchair. As the CNAs turned the lift toward the bed it began to sink because the lift arm couldn't handle the resident’s weight. In an attempt to complete the transfer before the patient was below the level of the bed, the CNAs swung the lift quickly toward the bed. The lift tilted dangerously to the side and the legs started to move together, narrowing the base of support. The resident dropped to the ground and the lift fell on top of him.

Disclaimer: Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
TIME LINE:

- CNAs get Hoyer lift and position it by resident's bed
- Resident is raised from wheelchair using the Hoyer lift
- CNAs swing resident toward bed
- Lift starts to collapse and tips to one side
- Resident drops to ground and lift falls on resident

Use a flipchart or sticky notes to draw a preliminary time line. Before proceeding to Step 4 of the RCA, be sure that everyone agrees that the time line represents what actually happened. Now is the time for the team to add missing steps or clarify “factual” inconsistencies about the event.

 Helpful Tips:

- The time line of the event should describe just the facts – not what caused the facts to happen. For instance, the CNAs may have mistakenly used a Hoyer lift that was not strong enough to move a tall resident weighing 300 lbs. This factor may have contributed to the event, but it is not documented in the time line. Only the facts of what happened should be included in the time line, the causal factors are added in a later step.
- Once the preliminary time line has been created, the facilitator finalizes the time line by asking the team:
  - Does the time line adequately tell the "story" of the incident? If not, the scope of the timeline may need to be extended further back in time or expanded to include what happened after the event.
  - Does each step in the time line derive directly from the step it precedes? If each step is not derived logically from the one preceding it, it usually indicates that one or more steps in the sequence have been left out. Add missing steps to the time line.
  - Is each step in the timeline pertinent to the incident under investigation? The answer may be "yes", "no," or "not sure." Include only the "yes" and "not sure" steps in the final event line.
- In rare situations the team cannot identify a sequence of steps leading up to the harmful event. For instance, when a resident develops an intravenous (IV) catheter–related infection it may not be possible to pinpoint the exact steps preceding the infection event. The infection appears to have occurred despite staff members apparently doing all the right things (e.g., following good hygiene when inserting catheters and caring for catheterized residents). In these situations, a time line is not created – however don’t jump to this conclusion too quickly. It is harder to find all the root causes of an undesirable event if the team does not have a time line to guide their decisions.
- Resist the temptation to skip right to step 5 of the RCA process, which is “Identify the root causes.” Team members may insist the root causes of the event are already understood and it is not necessary to go through steps 2 through 4. Jumping to conclusions about root causes increases the likelihood the team will end up with “quick-fix” solutions that do not address the underlying systems gaps, or contributing factors, and fail to prevent similar events in the future.
Step 4: Identify the contributing factors

Here is where the knowledge gained during step 3 is used by the team to dig deeper into what happened to discover why it happened.

Step 4 involves the team looking at each step of timeline and asking, “What was going on at this point in time that increased the likelihood the event would occur?” These are the contributing factors – situations, circumstances or conditions that collectively increased the likelihood of an incident. By itself a contributing factor may not have caused the incident, but when they occur at the same time, the probability an incident will occur increases.

As mentioned in Step 2, it is important to get the perspective of people personally involved in the event when identifying the contributing factors at each step. These may be the only individuals aware of the actual circumstances affecting what happened. For instance, the CNA who chose the wrong type of lift might have felt pressured by her supervisor to find a lift as quickly as possible so the resident would not be kept waiting. Team members not personally involved in the event might be unaware this contributing factor existed.

Below are examples of contributing factors that might be identified for each step of the timeline for the event involving a resident injury during transfer from wheelchair to bed.

- **TIME LINE:**
  - CNAs get Hoyer lift and position it by resident’s bed
  - Resident is raised from wheelchair using the Hoyer lift
  - CNAs swing resident toward bed
  - Lift starts to collapse and tips to one side
  - Resident drops to ground and lift falls on resident

- **CONTRIBUTING FACTORS:**
  - CNAs had to hurry to find a lift so resident would not be kept waiting
  - No sign on lift indicating weight limit
  - Resident was moved rapidly toward bed because lift arm started to slip
  - Sharp movement of resident by CNAs
  - Lift not strong enough to hold resident
  - CNAs unaware the lift they are using is not rated for use with very heavy residents
  - Facility’s one heavy duty lift was being used in another location

- **EVENT**
  - Resident drops to ground and lift falls on resident

- Helpful Tips:
  - Consider what was happening at each step in the time line to ensure the team does not overlook some important factors. Whenever possible, use a time line as the basis for identifying contributing factors.
  - Brainstorming can be an effective tool to identify contributing factors by asking, “What might have happened that would increase the likelihood the event would occur?” Consider what recommended practices might not have been followed, e.g. sterile dressing changes not done for IV-catheter sites. Consider what procedure “work-arounds” might have occurred. Consider how staffing at the time of the event might have impacted the eventual outcome.
  - When identifying contributing factors be careful to avoid “hindsight bias.” Knowing the eventual outcome of a time line can influence how team members view activities leading up to the event. Remember to consider only those factors that were actually present and known to those involved at the time – not what was only realized after-the-fact.

Disclaimer: Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
Step 5: Identify the root causes

All incidents have a direct cause. This is the occurrence or condition that directly produced the incident. In the resident incident described in Step 3, the tilting and collapsing Hoyer lift is the direct cause of the accident. However, the direct cause is not the root cause.

Root causes are underlying faulty process or system issues that lead to the harmful event. Often there are several root causes for an event.

Contributing factors are not root causes. The team needs to examine the contributing factors to find the root causes. This can be done by digging deeper – asking repeated “why” questions of the contributing factors. This is called the “five why’s” technique, which is illustrated below.

This questioning process is continued until all the root causes are found. It is common to find the same root cause for two or more contributing factors.

 Helpful Tips:
  o The team must determine if they’ve truly identified a root cause, versus a contributing factor which requires the team to do more digging. Ask the questions below about each potential root cause identified by the team. If the answers are NO, then the team has identified root causes and they can stop the questioning process. If the answer to any question is YES, then the team may not have identified true root causes and needs to ask more “why” questions to get to the root causes. Keep asking these until you get to root causes.
    ▪ Would the event have occurred if this cause had not been present?
    ▪ Will the problem recur if this cause is corrected or eliminated?
  o The team should not make judgments about whether an individual did the right thing. This judgment is to be made by the manager responsible for evaluating the employee’s performance. The facilitator may need to remind team members that the RCA process is not where these judgments are to be made.

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The team facilitator should watch out for discussion “manipulation” during this stage. Some team members may try to divert attention from root causes originating in their department or direct the discussion away from root causes that will require additional resources or necessitate significant changes to how work is now being done. A successful RCA process requires frank and open discussions of the causes of the event.

A fishbone diagram can also be used to determine root causes; see the CMS QAPI website for more information on this tool.

**Step 6: Design and implement changes to eliminate the root causes**

In this step the team evaluates each root cause to determine how best to reduce or prevent it from triggering another harmful event. The key is to choose actions that address each root cause. These actions will generally require creating a new process or making a change to a current process. The steps to accomplish this are the same as those used in any type of PIP. Note that at this point, you may want to reevaluate the composition of your team to make sure you have included people who are part of the process being changed. It is a good idea throughout a project to make sure you have the right people on the team and to adjust membership as needed.

At least one corrective action should be developed to reduce or eliminate each root cause. Some action plans will be short-term solutions to fix a contributing factor, e.g. purchase an additional Hoyer lift rated for use by residents weighing over 250 lbs. But short-term solutions rarely fix root causes. For instance, in the example event the team also needs to recommend that a formal evaluation of future specialized equipment needs for residents be regularly incorporated into the facility strategic planning and budgeting process.

When developing corrective actions consider questions such as:
- What safeguards are needed to prevent this root cause from happening again?
- What contributing factors might trigger this root cause to reoccur? How can we prevent this from happening?
- How could we change the way we do things to make sure that this root cause never happens?
- If an event like this happened again, how could we stop the accident trajectory (quickly catch and correct the problem) before a resident was harmed?
- If a resident were harmed by this root cause, how could we minimize the effect of the failure on the resident?

Aim for corrective actions with a stronger or intermediate rating, based on the categories of actions below. Corrective actions that change the system and do not allow the errors to occur are the strongest.

**Stronger Actions**
- Change physical surroundings
- Usability testing of devices before purchasing
- Engineering controls into system (forcing functions which force the user to complete an action)
- Simplify process and remove unnecessary steps
- Standardize equipment or process
• Tangible involvement and action by leadership in support of resident safety; i.e., leaders are seen and heard making or supporting the change

**Intermediate Actions**
- Increase staffing/decrease in workload
- Software enhancements/modifications
- Eliminate/reduce distractions
- Checklist/cognitive aid
- Eliminate look alike and sound alike terms
- “Read back” to assure clear communication
- Enhanced documentation/communication

**Weaker Actions**
- Double checks
- Warnings and labels
- New procedure/memorandum/policy
- Training
- Additional study/analysis

For example, suppose staff members cannot locate the equipment to use when lifting larger residents, because the specialty equipment is not kept in the same location. The strongest action to prevent another accident would be to keep all equipment designed for special needs residents in just one storage area (change physical surroundings). Staff members will no longer need to differentiate “usual” equipment from “specialized” equipment. If this action is not feasible, consider placing a sign on the lift equipment – “**DO NOT USE FOR RESIDENTS OVER 250 LBS.**” This is an example of a warning or label (sometimes called a visual cue). It is a weak action because staff members might overlook the warning, but if no other stronger action is available, a weak action is better than none at all.

When designing corrective actions, clearly state what is to be done, by whom, and when. Satisfactory implementation of the corrective actions will be monitored so it is important to have clearly defined plans.

✔ **Helpful Tips:**
  - The team leader should encourage team members to come up with as many intermediate and strong actions as possible. It is helpful to involve supervisory and management staff in the action planning discussions. Designing intermediate and strong actions often requires an understanding of various resident care systems and the facility’s resource allocation priorities. Staff members on the team may not possess this knowledge.
  - Because the feasibility and costs associated with corrective actions must also be considered it is helpful to include facility management in the corrective action discussions, if they are not already members of the team.
  - If a particular action cannot be accomplished due to current constraints (e.g. lack of resources), the team should look for other ways of changing the process to prevent a similar event from occurring in the future. Doing nothing should not be an option.
Step 7: Measure the success of changes

Concurrent with implementation of action plans, mechanisms are established to gather data that will be used to measure the success of the corrective action. The RCA should reduce the risk of future harmful events by minimizing or eliminating the root causes. What you measure should provide answers to three questions:

1. Did the recommended corrective actions actually get done? (e.g., Did the warning signs get put on the Hoyer lifts? Did a formal equipment evaluation step get added to the annual budgeting process?)
2. Are people complying with the recommended changes (e.g., How often is the wrong type of Hoyer lift used for residents weighing over a predetermined weight? Is staff provided an opportunity to participate in an equipment needs assessment during the budgeting process?)
3. Have the changes made a difference? (Has another resident been harmed by equipment unsuited for their physical condition?)

Evaluating the success of the PIP usually occurs after the team has been disbanded, and will become the responsibility of the person designated to monitor the corrective action/s. The QAA committee is responsible for overseeing all QAPI activities, which includes reviewing data on the effectiveness of all improvement projects. Ideally, all of the following criteria should be met to conclude a PIP has been successful:
- Measures of success were monitored over time.
- The goal was attained (process changes were made and sustained, no recurrent events).
- You are confident that the change is permanent.
RCA PIP Template

This template can be used to document the completed RCA PIP process, including follow-up actions and measures. Revise it as necessary to meet your needs.

Team Facilitator: Date RCA Started: ____________________________ Date Ended: ____________

Team Members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Name</th>
<th>Position</th>
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Brief Narrative Description of Event (include time line if available):
**Root Causes and Contributing Factors**

Conduct your systematic analyses to determine your contributing factors and root causes. Use techniques such as the five whys, flowcharting, or the fishbone diagram to assist in identifying the root causes. Additional tools are available that guide the use of each of these techniques. It is helpful to keep any of these analyses with your PIP documentation for future reference. Describe each root cause as identified by the team. Enter these in the table below.

**Corrective Action Plans**

For each root cause identified, enter the corrective action plans intended to prevent the root cause from causing another harmful event. There can be more than one action plan for each root cause. Some action plans may be short-term interventions which can be accomplished quickly and some action plans require more long-term implementation steps. For each action plan designate the individual or group responsible for completing the action and the time frame for completion.

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Corrective Action</th>
<th>Responsible Individual/Group</th>
<th>Completion Deadline</th>
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### Measures of Success

<table>
<thead>
<tr>
<th>Corrective Action</th>
<th>Measures of Success (How we will know if this action is successful)</th>
<th>Reporting Schedule and Individual or Group Responsible for Reviewing Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consider measures of how often recommended processes are not followed and the incidence of similar adverse events.</td>
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Signature of RCA team leader________________________________________ Date

Overview: Failure Mode and Effects Analysis (FMEA) is a structured way to identify and address potential problems, or failures and their resulting effects on the system or process before an adverse event occurs. In comparison, root cause analysis (RCA) is a structured way to address problems after they occur. FMEA involves identifying and eliminating process failures for the purpose of preventing an undesirable event.

When to use FMEA: FMEA is effective in evaluating both new and existing processes and systems. For new processes, it identifies potential bottlenecks or unintended consequences prior to implementation. It is also helpful for evaluating an existing system or process to understand how proposed changes will impact the system. Once you have identified what changes need to be made to the process or system, the steps you follow are those you would use in any type of PIP.

Directions: Use this guide to walk through FMEA. FMEA is a tool that will allow nursing homes to proactively identify and reduce potential failures within an existing or a proposed process. FMEA is very similar to what most people do every day. We try to anticipate what might go wrong and do what we can to prevent this from happening or minimize the effects. For instance, before leaving your home for work, you listen to the radio or television to find out where there may be traffic jams or delays in public transportation. By knowing if there are problems on the road, you can make changes to your driving route or mode of transportation to ensure you get to work on time. By knowing what might go wrong, you can make changes that reduce or prevent something from going wrong.

Facilities accredited by the Joint Commission or in states with regulations governing completion of FMEAs should refer to those requirements to be sure all necessary steps are followed.

Below is a quick overview of the steps of FMEA.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select a process to analyze</td>
<td>Choose a process that is known to be problematic in your facility or one that is known to be problematic in many facilities.</td>
</tr>
<tr>
<td>2. Charter and select team facilitator and team members</td>
<td>Leadership should provide a project charter to launch the team. The facilitator is appointed by leadership. Team members are people who are directly involved in the process to be analyzed.</td>
</tr>
<tr>
<td>3. Describe the process</td>
<td>Clearly define the process steps so that everyone on the team knows what is being analyzed.</td>
</tr>
<tr>
<td>4. Identify what could go wrong during each step of the process</td>
<td>Here is where the people directly involved in the process describe the problems that can or do occur.</td>
</tr>
<tr>
<td>5. Pick which problems to work on eliminating</td>
<td>The focus of improvements will be on those problems that happen quite often and/or or have a significant impact on resident safety when they do occasionally occur.</td>
</tr>
<tr>
<td>6. Design and implement changes to reduce or prevent problems</td>
<td>The team determines how best to change the process to reduce the risk of residents being harmed.</td>
</tr>
<tr>
<td>7. Measure the success of process changes</td>
<td>Like all improvement projects, the success of improvement actions is evaluated.</td>
</tr>
</tbody>
</table>

Disclaimer: Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
Step 1: Select a process to analyze

Nursing homes are complex organizations and involve processes in many areas, such as resident care, business operations, environmental services, and others. You can use FMEA to examine processes in any of these areas to proactively reduce risks to patient safety and improve quality of care and quality of life for residents.

When conducting FMEA on an existing process, consider selecting a process that is known to be problem-prone or potentially risky. For instance, do staff members consistently perform skin assessments promptly after admission? FMEA can be used to identify gaps and develop actions to make the process more efficient and safe. FMEA also helps to prepare for implementation of new processes. Are you concerned about how you will implement electronic health records? FMEA promotes systematic thinking in terms of “What challenges will we encounter? What can we do to meet these challenges?”

Ask your employees what activities or processes have not yet provided the desired result. They may tell you there is a safety concern related to monitoring cognitively impaired individuals who like to wander. You can do FMEA on your process for regularly assessing these residents and protecting those found to be vulnerable for injury or elopement.

 Helpful Tips:

- Be sure an identifiable process is chosen for FMEA. Instead of, “We will do FMEA on the problem of unexplained weight loss among some residents,” consider doing FMEA on the process used in your facility to prevent residents from having an unexplained weight loss. Unexplained weight loss is an outcome, not a process. A process is a series of actions or steps taken to achieve an end.
- Narrow the scope of FMEA as much as possible. For instance, when facilities try to do a project on a complex process such as medication administration the team often finds there are too many variables to take into account. The administration process can vary by unit, by type of medication, by time of day, and so on. It is best to narrow the focus. For instance, do FMEA on administration of a particular type of high-risk medication or a project on medication administration for a category of residents vulnerable to safety problems.
- To get employees to support FMEA and make necessary process changes, senior management should consult staff members about processes they believe are challenging.
- Consider using FMEA to evaluate new processes. It is a good technique for anticipating what could happen so processes can be made safer before full implementation.
Once it is decided that a Performance Improvement Project (PIP) will be conducted on a process using FMEA, leadership should begin by designating a facilitator for this team. Together they should create a charter that will help guide the team in managing the scope of the project and ensure the implemented changes reflect the FMEA findings. They should also work together in selecting staff to participate on the PIP team.

The facilitator is often someone already involved in QAPI in the facility. As managers, supervisors, and staff members gain experience in doing FMEA, more people in the facility can be trained to serve as FMEA facilitators.

The direct care staff selected to serve as team members should have day-to-day responsibilities for completing one or more steps in the process under analysis. A personal knowledge of what actually happens, not what should happen, is vital to the project success.

The number of people on a team depends on the scope of the process review. There should be at least one representative from each employee group involved in the process. For instance, if the project is aimed at the process of assessing residents for fall risk and protecting those found to be high risk, the team should include representatives from nursing (RN or LPN), direct care staff (nurse assistant or CNA), housekeeping, and physical therapy. Consider physician involvement when the process includes steps that involve physicians.

✔ **Helpful Tips:**

- Minimize the number of management or supervisory level individuals on the team. Staff members may be inhibited from speaking up during critical discussions about process problems if their direct supervisor is in the room.
- Involve direct care staff and those who have direct experience with the process being analyzed. It is important to understand the process as it is actually performed, including why staff make mistakes and develop work-a-rounds.
- Include people from all shifts on the team, when possible. The experiences of staff working during the day may be much different than what happens during the evening and night shift. A successful FMEA is highly dependent on the ability of the team members to understand how a process now functions and what occasionally goes wrong.
- It can sometimes be tempting to complete FMEA by interviewing those involved in the process, without any formal meetings of the team. While this might move the analyses along quicker, the frank discussions that occur during team meetings are more likely to lead to a successful FMEA – one that actually improves the safety of a high-risk resident care process.
Step 3: Describe the process

At the first meeting, the team clearly defines the process to be analyzed. The best way to do this is to construct a flowchart of the steps. (See the QAPI Flowchart Guide for more information on creating flowcharts) Using sticky notes, write down the first step in the process and each subsequent step. The process description does not need to be detailed. A high-level flowchart, with just the major steps identified, is usually sufficient.

The example below shows the steps in the process of starting Coumadin for residents not currently on this anticoagulant. The process starts with the physician ordering Coumadin for a resident and ends with ongoing monitoring of the patient’s INR (a measure of blood coagulation) and clinical status.

![Flowchart of Coumadin Administration Process]

Starting with a clear description of the process ensures that everyone on the team understands what is being analyzed. Once the team members agree that the process is clearly and accurately described, move to step 4.

If there is confusion about the actual process steps or if people cannot agree on what the process entails, do not continue on to step 4 of the FMEA. It may be necessary to refine the scope of the FMEA. For instance, one nursing home started FMEA on the process of admitting new residents. While describing the process, team members found that admission steps varied somewhat on the weekends. They chose to concentrate their analysis on the weekend admission process because it seemed to be the most problem-prone. They agreed to later do FMEA on weekday admissions.

✓ Helpful Tips:

- If team members cannot agree on how the process currently works in their area and the process scope cannot be narrowed to obtain agreement, it usually is a signal of a very unreliable process. An unreliable process is one that is not performed consistently – people pretty much do whatever works best for them. FMEA should not be done on this process; instead, do a performance improvement project that is aimed at creating a redesigned standard streamlined process. Once that new process is designed, consider doing FMEA to reduce or eliminate mistakes that may occasionally occur.

- For a complex process with many steps, it may be better to do several FMEAs by breaking-up the process into manageable bites. By focusing on just one part of the process, the team can complete the FMEA in much shorter time. For instance, there are several major steps to the process of identifying residents at high risk for falls and preventing falls in this group of residents. The team could do FMEA just on the assessment phase of the process and another on the prevention phase.
Step 4: Identify what could go wrong during each step of the process

Here is where the knowledge and experience of team members are vital. For each process step identified in step 3, the team determines what can go wrong or what can fail (commonly called the failure modes). The people doing the work every day are in the best position to know what can (and does) go wrong.

This step is similar to a brainstorming session where people generate ideas and come up with solutions to problems. At this point, team members are generating a list of the failures that can occur at each step of the process being analyzed. Below are examples of things that could go wrong during the step of “Physician initiates Coumadin therapy for a resident.”

<table>
<thead>
<tr>
<th>Physician initiates Coumadin therapy for a resident</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Could Go Wrong (failure modes)</td>
</tr>
<tr>
<td>1. Order not entered into computer</td>
</tr>
<tr>
<td>2. Order not communicated to Pharmacy</td>
</tr>
<tr>
<td>3. Wrong dosage ordered</td>
</tr>
<tr>
<td>4. Physician unaware Coumadin is contraindicated for this resident</td>
</tr>
</tbody>
</table>

After the possible failures are identified for one step, the team moves on to identifying failures that might occur in the next step. Step 4 is complete when the team is satisfied all possible failures have been identified for each step.

Helpful Tips:

- Create an atmosphere where staff participating in the FMEA feel safe talking about process mistakes, or work-arounds that occur. To decrease “protectionism” where staff are reluctant to talk about mistakes made by the peer group they represent, make it clear from the beginning that everyone sometimes makes a mistake and it is not a sign of incompetence; rather most mistakes are the result of a poorly designed process.
- Do not let this brainstorming session become a finger-pointing exercise. Keep the team members focused on the goal of the FMEA – that is to identify and then reduce or eliminate failures by improving the process.
- Write the failures on sticky-notes (one per note) and line them up beneath the sticky notes you created for the process steps. When the team members are done identifying failures for each step, they will have a clear visual picture of the entire process and the failures that could occur at each step.
- Sometimes it is helpful to get additional staff input into this step. Ask team members to gather more ideas as to what can go wrong by sharing the team’s preliminary findings with others in their employee group. Bring these ideas back to the next team meeting for discussion and possible addition to the failure lists.
Step 5: Pick which problems to work on eliminating

It is common for project teams to identify several different mistakes that might occur at each step in the process under study. However, changing the process to reduce or eliminate every one of these mistakes is time-consuming, may not be feasible, and often not necessary. Some mistakes rarely happen, some are so obvious that the mistake is easily caught and corrected, and some have little impact on resident safety. In step 5 of the FMEA, the team selects which failures will be the focus of improvement actions.

Selection of the failures to work on eliminating is based primarily on two factors: how likely the failure will actually occur and how the failure will affect the resident should it occur. For each failure, the team decides:

- What could happen should this failure occur? (outcome)
- How serious would the outcome be? (severity)
- How often is this failure likely to occur? (probability)

**Determine outcomes**

Starting with the first step in the process, the team considers each failure that was identified in step 4 – answering the question, “What would happen if this failure occurs?” Sometimes what would happen is that the resident will experience some type of adverse outcome. Sometimes what would happen is that needed treatment or therapy would be delayed. For example, “What would happen if the physician’s order for Coumadin is not entered into the computer?” Team members may agree that this computer entry failure will be caught fairly quickly and corrected, so the resident most likely will not be harmed. In this situation, the outcome for this failure would be a delay in administration of Coumadin.

The team methodically goes through each failure identified during step 4 and determines what would happen if this failure occurs.

**Determine seriousness of the outcomes**

This decision can be made by the team while they are identifying the outcomes or the seriousness can be determined after all outcomes have been determined. For each outcome, the team must decide how “bad” the particular outcome would be for the resident. This is a subjective judgment made by team members based on their knowledge and experience.

Sometimes facilities use a numeric rating scale to establish the seriousness of the outcome. Below is the rating scale that could be used in nursing homes. The severity rating scale is adapted from the Healthcare Failure Mode and Effects Analysis (HFMEA) model developed by the National Center for Patient Safety of the Veterans Health Administration.
Outcome severity rating scale

<table>
<thead>
<tr>
<th>Rating</th>
<th>Outcome Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Catastrophic</td>
<td>Resident experiences death or major permanent loss of function (sensory, motor, physiologic, or intellectual),</td>
</tr>
<tr>
<td>4</td>
<td>Major</td>
<td>Resident experiences permanent lessening of bodily function (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, or increased level of care for 3 or more days.</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>Resident experiences an event, occurrence, or situation which could harm the resident but will not cause permanent injury or lessening of bodily function or require the delivery of additional healthcare services</td>
</tr>
<tr>
<td>2</td>
<td>Minor</td>
<td>Resident may experience a minor injury, but most likely would not be affected by the failure and it would not cause any changes in the delivery of care.</td>
</tr>
<tr>
<td>1</td>
<td>Near miss</td>
<td>Resident would not experience any injury, changes in delivery of care, or an increased level of care.</td>
</tr>
</tbody>
</table>

Numeric severity rankings are not required to be used in a FMEA. It can be just as effective (and perhaps less intimidating) to have the team rate outcomes using descriptive terms such as:

- Low (minimal resident harm)
- Moderate (short-term resident harm)
- Severe (permanent or long-term harm)
- Fatal (death)

Using a decision-making process such as nominal group technique or multi-voting, the team methodically agrees to a severity ranking for each outcome.

**Determine Probability**
The team now judges how often each failure is likely to occur.

Rating scales can help to standardize the team members’ responses. Below is the probability rating scale adapted from the Healthcare Failure Mode and Effects Analysis (HFMEA) model developed by the National Center for Patient Safety of the Veterans Health Administration.
### Failure probability rating scale

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Very high probability: failure is most inevitable</td>
<td>1 failure in 5 attempts</td>
</tr>
<tr>
<td>4</td>
<td>High: repeated failures</td>
<td>1 failure in 50 attempts</td>
</tr>
<tr>
<td>3</td>
<td>Moderate: occasional failures</td>
<td>1 failure in 500 attempts</td>
</tr>
<tr>
<td>2</td>
<td>Low: relatively few failures</td>
<td>1 failure in 5000 attempts</td>
</tr>
<tr>
<td>1</td>
<td>Remote: failure is unlikely</td>
<td>&lt;1 failures in 500,000 attempts</td>
</tr>
</tbody>
</table>

### Prioritize Failures for Improvement Action

The team goes through the process of identifying failure outcomes and outcome severity and determining failure probability so that priorities for action can be established. If at the outset the team concludes it is important to reduce or eliminate all failures, the exercises described above are not necessary as the team has already set its action priorities. It can move onto step 6 of the FMEA.

More likely the team will find some failures inconsequential – although they do happen every once in a while they do not adversely affect residents. The exercises described above can help the team make this decision.

Which failures should be chosen for action? There are no absolute rules for answering this question. Any failure that is likely to result in catastrophic or major harm to a resident is a good first choice for action. Additionally, any failure that occurs quite often and has the potential for harming a resident should be considered for action. After the team has prioritized the failures that will be the focus of improvement actions, the FMEA moves to step 6.

**Helpful Tips:**

- When defining outcomes that will occur following a failure, choose the most likely outcome not the worst case scenario. Do not forget that outcomes for some failures are delays in treatment or services which may not cause resident harm and may actually go unnoticed by the resident. If the outcome from every failure is classified as catastrophic or major then the team will need to develop improvement actions for every failure.
- It can sometimes be problematic for team members to judge how often a failure might occur. Sometimes there is a tendency to seek the “right” answer when, without any prevalence data, a correct answer is not possible. In the absence of data, ask the team members to estimate based on their experience and a sense of what happens in the facility. For instance, despite facility policies requiring confirmation of resident identity prior to giving medications, nurses admit that in practice, for a variety of reasons, they fail on occasion to do this safety check. Ask the nurses on the team to estimate how often they think this failure occurs. A more accurate estimate of failure probability might be obtained if management level personnel are not in the room.
- Setting priorities for improvement is challenging. The team leader and members should openly acknowledge and work to address barriers that can impact the priority-setting process. Watch out for:

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Fears of “winners and losers.” If a team member worries that a change in their area could adversely affect them, they may try to guard their own “turf” by strongly advocating that failures in other areas must be dealt with first.

Thinking the team can “do it all” and there is no need to prioritize. If people feel uncomfortable admitting that they cannot improve all areas at once, they will resist setting priorities.

Without a clear leadership commitment to improving resident safety, team members may fear that the group’s priorities will be overturned or go nowhere.

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**Step 6: Design and implement changes to reduce or prevent problems**

In this step the team evaluates each failure chosen for action for the purpose of designing and implementing process changes to reduce or prevent the failure from occurring. This step is similar to the action planning phase in any type of improvement project.

To determine how the process should be changed the root cause of each failure chosen for action must be identified. The team may need to gather additional input from other staff members to help in determining the root causes of failures. For instance, why does a physician order for Coumadin not get entered into the computer? Why is the order not communicated to the pharmacy when it does get entered into the computer? The Five Whys technique is a good way to drill-down to find the root cause of failures. The answer to the first "why" prompts another "why" and the answer to the second "why" prompts another and so on; hence the name the Five Whys.

Once the cause of each failure is clear, the team develops actions to reduce or eliminate the failure. When developing these actions consider questions such as:

- What safeguards are needed to prevent this failure from happening?
- What would have to go wrong to have a failure like this happen? How can we prevent this from going wrong?
- How could we change the way we do things to make sure that this failure never happens?
- If a failure like this happened, how could we quickly catch and correct the problem before the resident ended up being harmed?
- If the resident were harmed by this failure, how could we minimize the effect of the failure on the resident’s condition?

Aim for corrective actions with a stronger or intermediate rating, based on the hierarchy suggested by the examples below. Corrective actions which focus on designing controls into the system that do not allow errors to occur and rely less on any one person’s actions are the strongest. The feasibility and costs associated with actions must also be considered.

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*Stronger Actions*

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• Change physical surroundings
• Usability testing of devices before purchasing
• Engineering controls into system (forcing function), which force the user to complete an action
• Simplify process and remove unnecessary steps
• Standardize equipment or process
• Tangible involvement and action by leadership in support of resident safety; i.e., leaders are seen and heard making or supporting the change

Intermediate Actions
• Increase staffing/decrease in workload
• Software enhancements/modifications
• Eliminate/reduce distractions
• Checklist/cognitive aid
• Eliminate look alike and sound alike terms
• “Read back” to assure clear communication
• Enhanced documentation/communication

Weaker Actions
• Double checks
• Warnings and labels
• New procedure/memorandum/policy
• Training/in-service
• Additional study/analysis

For example, suppose Coumadin orders do not get entered into the computer because the person receiving the phone order gets busy and forgets to enter the order. The strongest action to prevent this from happening might be to use a Coumadin standing order protocol so that phone orders for this purpose are eliminated or reduced. Decreasing staff workload might reduce the number of orders that do not get entered, although unexpected situations can arise that divert people’s attention even when staffing is sufficient. How about something as simple as writing phone orders on sticky paper that can be adhered to the computer screen? This would cause the order to stay visible until someone has time to enter the order. This is an example of a warning or label (sometimes called a visual cue). It is a weak action because the sticky paper can fall off or be taken off by someone in a hurry to access the computer for another purpose. But if no other strong action is available, a weak action is better than none at all.

When designing actions, clearly state what is to be done, by whom, and when. Satisfactory implementation of the actions will be monitored later, so it is important to have clearly defined action plans.

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Helpful Tips:
○ Do not design actions to prevent failures until the team has a good understanding of what can cause the failures to occur. “Blindly” changing the process in hopes of preventing failures is likely to be unsuccessful and may actually make the process less safe if the changes increase complexity.
○ The team facilitator should encourage team members to come up with as many intermediate and strong actions as possible. It is helpful to involve supervisory and management staff in the action planning discussions. Designing intermediate and strong actions often requires an understanding of various resident care systems and the facility’s resource allocation priorities. Staff members on the team conducting the FMEA may not possess this knowledge.

Step 7: Measure the success of process changes

Concurrent with implementation of action plans, mechanisms are established to gather data that will be used to measure the success of the corrective action. The goal of a FMEA is to reduce the risk of process failures and improve resident safety. What you will measure is how often the process failures identified as high priority to fix (step 5) are still occurring after process changes (step 6) are completed. Plus you will measure the incidence of adverse events related to the process under study (for example, the number of residents on Coumadin that develop a Coumadin-related complication). Some of this data may be available through incident reporting, MDS resident assessments, state survey results, resident satisfaction surveys, and other established sources of performance data. Occasionally a new data collection effort is needed to gather information needed for the results of the FMEA.

Evaluating success of the PIP usually occurs after all process changes have been implemented and will become the responsibility of the person designated to monitor the corrective action/s. The QAA committee is responsible for overseeing all QAPI activities, which includes reviewing data on the effectiveness of all improvement projects.

Ideally, all of the following criteria should be met to conclude the PIP has been successful:
● Measures of effectiveness were monitored over time.
● The goal was attained (fewer failures, better outcomes).
● You are confident that the change is permanent.
FMEA PIP Template

This template can be used to document the completed FMEA including follow-up actions and measures. Revise this template as necessary to meet your needs. Review the Guidance for Failure Mode and Effects before using this template.

Process analyzed:

TEAM leader/facilitator: ________________________________
Date FMEA started: ____________ Date ended: ____________

Team members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Name</th>
<th>Position</th>
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</table>

Describe your process steps (flowchart): As per the suggested guidance, you might use sticky notes on separate papers.

Identify what could go wrong during each step of the process. You might use sticky-notes indicating what could go wrong for each step. Line these up beneath each process step.

For each item identified that could go wrong, rate each for the seriousness of this outcome (severity) and how often the mistake is likely to occur (probability) (per the suggested guidance and your rating scale preferences). Indicate these ratings on the sticky notes that identify what could go wrong.

Review your ratings and decide on your process failures identified as high priority for improvement actions. List the process failures you will focus on in the table below.

Disclaimer: Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
**Describe your corrective actions for process failures identified as high priority:** Before determining your corrective actions for process failures, consider whether you should conduct a systematic analysis to determine the root cause of each failure chosen for action. If necessary, use techniques such as the five whys, flowcharting, or the fishbone diagram to assist in identifying the root causes. Additional tools are available that guide the use of each of these techniques. It is helpful to keep any of these analyses with your PIP documentation for future reference. In the table below, describe each root cause for each process failure, and then enter your specific actions to reduce or eliminate the failure, your completion timeframe, and the responsible individual or group.

<table>
<thead>
<tr>
<th>Process Failure</th>
<th>Root Cause of Process Failure</th>
<th>Specific Actions to Reduce or Eliminate the Failure</th>
<th>Completion Time Frame</th>
<th>Responsible Individual/Group</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
# Measures of Success

<table>
<thead>
<tr>
<th>Corrective Action</th>
<th>Measure(s) of Success (How we will know if this action is successful) (Consider measures of how often the failure is still occurring after process changes and the incidence of adverse events related to the failure)</th>
<th>Reporting Schedule and Individual or Group Responsible for Reviewing Results</th>
</tr>
</thead>
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Signature of FMEA leader/facilitator________________________________________________________ Date
________________________________________________________________________