Revision C – 11/04/2019

Radiation
Patient Safety Committee
Toolkit

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OVERVIEW OF THE ONCOLOGY PATIENT SAFETY COMMITTEE

Oncology Patient Safety Committees at St. Elizabeth Healthcare are an important component of ensuring our members receive the safest care possible during every encounter with staff. These Committees are charged with implementing initiatives to enhance safety practices in all Oncology areas and every facility where Oncology services are provided.

Our Patient Safety Program is a comprehensive plan designed to improve patient safety, reduce the risk to our patients and decrease medical errors. We accomplish this by: Reporting and analyzing errors and continuously improving our care delivery processes to reduce and prevent errors.

This toolkit is available to assist Oncology Patient Safety Committees in creating, growing and maintaining a heightened sense of awareness for the safety of our patients. It provides an overview of the Oncology Patient Safety Program and a comprehensive set of tools to use during any stage of this journey.

Why was this toolkit created?

- To provide information and tools for the implementation and sustainment of a Patient Safety Committee.
- To provide orientation information for new Patient Safety Committee members.
- To standardize information and tools used by the Oncology Patient Safety Program at St. Elizabeth Healthcare.
- To provide general information about Patient Safety and High Reliability Organizations.

How can the toolkit help you?

This toolkit is a resource for starting, growing and sustaining a Patient Safety Committee. It is broken down into chapters, so the relevant information and tools are easy to find.

Below are examples of how you can use the toolkit:

- If you are creating a Patient Safety Committee, review Chapter 2 for suggested steps and templates so you do not need to start from scratch.
- If you have new members of your Patient Safety Committee, use this toolkit as an “orientation” tool and expectations of the Oncology Quality and Patient Safety Committee.
- If you have a Patient Safety Committee and want ideas of what to do next, review Chapter 3 for suggestions.

Chapter 1 – Charter Example

Note: See Charter Template in the Appendix.

Purpose and Objectives: The purpose and objectives of the Radiation Patient Safety Program include developing, implementing and maintaining a proactive process that promotes patient safety and enhances the quality of care and service provided to patients. The primary tool used to measure and track patient safety events in Midas. The Radiation Patient Safety Program depends on consistent, accurate and timely reporting of safety events in all Oncology Specialty Departments. The primary purpose of the program includes investigating and responding to reported clinical 'system' and 'process' areas of concern. The Radiation Patient Safety Program will be overseen by the Oncology Quality and Patient Safety Committee chaired by the Oncology Quality Director. All Radiation Department staff are welcome to participate.

Scope: The Radiation Patient Safety Program encompasses all outpatient Radiation Treatment areas at Edgewood and Ft. Thomas.

Out of Scope: All Inpatient hospitals and medical offices other than patient delivery practices directly related to the ambulatory Radiation Department.

Program Priorities: The Patient Safety goals and objectives are updated and revised as necessary with oversight from the Oncology Quality and Patient Safety Committee (**OQPSC**).

Structure/Oversight: The Oncology Quality and Patient Safety Committee partners with Risk and General Council as well as the Oncology Medical Director in oversight of the Radiation Patient Safety Committee in order to achieve national and regional (Northern Kentucky) patient safety objectives as adopted by the OQPSSC.

The **Oncology Quality and Patient Safety Committee (OQPSC)** will assist in assessing and addressing potential risks/harms to patients and reported patient safety near misses, errors, and safety concerns that may require additional sponsorship from a Leadership level.

Expectations for the Radiation Patient Safety Committees are to:

1. Identify departmental risks to patient safety and report them in Midas.
2. Review and share data and information on patient safety events.
3. Review and share data on system issues that could affect patient safety.
4. Educate and train staff on patient safety principles and tools.
5. Develop Standard Work when it will help ensure Radiation Patient Safety.
6. Identify collaborative relationships between the system level patient safety, infection control and other departments as necessary.

Membership: The Director of the Radiation department will either choose someone to lead this committee or lead the committee themselves. The Director of Radiation will also decide how many members will be manageable and adequate to maintain a productive committee. In general, all staff are welcome to be part of the committee, and others may from time to time visit these open meetings and/or present information on specific Safety Events or other topics.

SPONSORSHIP: The Radiation Patient Safety Committees have the support of both the Oncology Quality and Patient Safety Committee, Senior Vice President Patient Care Services / Cancer Care, the Oncology Medical Director and the Associate General Counsel-Risk Management.

MEETING SCHEDULE: The Radiation Patient Safety Committees will meet on a regularly scheduled basis, no less than every other month.

RECORDS AND MINUTES: Minutes documenting the proceedings of each meeting, including attendance, key discussion points and decisions made, are recorded and approved at the subsequent meetings of each of the three Committees.

CONFIDENTIALITY: The Committee is responsible for the confidentiality of patient and physician/staff information and for protection of that data from loss, tampering or unauthorized use. All committee members and/or staff should understand the employee policy on confidentiality, including the penalties for unauthorized use of information.

Data that could clearly identify individuals, patients, physicians, or staff to persons outside St. Elizabeth SEH and SEP must be removed from all summary reports. If there are any questions related to confidentiality, please contact Risk Management at (859) 301-6260.

All documents (reports, minutes, agenda and memos) must be labeled confidential and distributed only to Committee members and/or appropriate administrators. All filed documents (paper or computer files) must be protected from access by unauthorized persons. All documents no longer in use must be destroyed.

QUALITY REVIEW PROTECTIONS: The activities of this Committee are not always protected from legal discovery so great care must be taken for security and confidentiality. All serious occurrences (i.e., those involving a safety hazard, serious injury or death, a threat to sue, or any other situation involving potential liability) are telephoned to or discussed in person with Risk Management.

CHAPTER 2 – ESTABLISHING A PATIENT SAFETY COMMITTEE

Checklist for Creating a Patient Safety Committee

Establishing a Patient Safety Committee is both exciting and challenging. This chapter provides suggested steps and resources to assist you as you begin this journey.

Below are steps that should be followed to create an Oncology Patient Safety Committee and prepare for the first meeting. The pages that follow provide additional detail and resources for each item below.

□ Identify and Select an Executive Sponsor(s) and/or Physician Champion

□ Identify and Select Committee Chair(s)

□ Identify and Select a Physician Champion

□ Determine Patient Safety Committee Membership Size

□ Determine the Patient Safety Committee Schedule

□ Identify and Select Patient Safety Committee Members

□ Draft the Committee Charter

□ Create the Agenda for first Patient Safety Committee meeting

□ Midas Reports

STEP 1: Identify an Executive Sponsor - This is a vital first step that will help ensure the success of any newly formed Patient Safety Committee. This person does not need to be clinical but should be someone in a leadership position with decision making authority regarding the Oncology Patient Safety Program.

Role of the Executive Sponsor:

- **Primary Role:** Remove barriers as escalated by the Patient Safety Committee's Chair(s)
- Commit to working with staff to improve patient safety within the Radiation Department.
- Provide charge and direction to the Patient Safety Committee's work when/if necessary
- Ensure the Patient Safety Committee's work remains in alignment with organizational priorities
- Provide protected time for Chair(s) and members to actively participate in the Patient Safety Committee
- Assist the Patient Safety Committee with prioritizing efforts when appropriate

NEXT STEPS – Now that you have identified an Executive Sponsor, begin planning and executing the items below. These should all be in place prior to your first Patient Safety Committee meeting.

Identify and Select Committee Chair(s)

Each Patient Safety Committee must have at least one Committee Chair but will ideally have two (Co-Chairs) – so when one is unable to attend a meeting, the other will assume The Chair's duties. It is crucial that these individuals are well respected among their peers, passionate about patient safety, and have the capacity to guide the Patient Safety Committee's work. Ideally, the Chair(s) will be different than the Executive Sponsor. However, it is not a requirement.

Role of the Committee Chair(s):

- Lead Committee meetings
- Set Patient Safety Committee agendas
- Escalate issues/barriers to Executive Sponsor when appropriate
- Maintain a safe environment where all members feel comfortable to speak openly
- Ensure each member's voice is heard
- Ensure scope and time is respected during PSC meetings
- Obtain approval of written minutes from PSC members
- Ensure at least one representative regularly attends the Oncology Quality and Patient Safety Committee meetings and provides an update to the OQPSC.

Identify and Select a Physician Champion

Having a Physician Champion on the Patient Safety Committee (PSC) will be important to the success and engagement of physicians in any initiatives and/or work that comes from the PSC. She/he does not need to be a formal leader but should be respected among his/her peers and be passionate about patient safety. This step should be completed before the PSC membership is selected because the Physician Champion can help recruit additional physicians to participate on the PSC. This person can also be one of the Patient Safety Committee (PSC) Chairs.

Role of Physician Champion:

- Actively participate in the Patient Safety Committee (PSC) meetings
- Encourage other physicians to participate in the PSC and its work
- Champion patient safety among colleagues

Determine Patient Safety Committee Membership Size

The members should be broadly representative of the Department it represents – see **Identify and Select Patient Safety Committee Members** below. This step should be completed before you select the PSC members.

Identify and Select Patient Safety Committee Members

When recruiting members for the Patient Safety Committee (PSC), seek out individuals who are passionate about patient safety (no matter their experience), both informal and formal leaders, should have good communication skills, and have protected time to be engaged. There is no requirement for the percent of physicians vs. non-physicians on the PSC. However, the membership should reflect all the department's staff. (Keep it small. Fewer members will progress faster.) Please Note: members do not have to be clinical to be on the committee. It will also be important to have someone with Manager (report creation) access in Midas.

Before a staff member agrees to participate on the Committee ensure they are aware of the following:

- Expectations of the Patient Safety Committee (PSC) – (See "Overview" before Page 1)
- Roles and Responsibilities of the PSC Members
- Time Commitment

Role of Patient Safety Committee Members:

- Regularly attend Patient Safety Committee (PSC) meetings
- Actively engage in PSC meetings including sharing opinions, experiences, and suggestions
- Keeps discussions from PSC meetings confidential
- Assists in prioritizing the Patient Safety work of the Committee
- Acts as a liaison between the PSC and their department/area
- Helps spread important safety messages among colleagues

Membership List Template – (See Page 14)

Determine the Patient Safety Committee Schedule

RADIATION PATIENT SAFETY COMMITTEE (PSC) should meet no less than quarterly. However, ideally the Committee would meet more often (monthly or weekly, or twice monthly) so that patient safety issues do not go a long time without resolution. Since confidential information will be discussed during PSC meetings, after the schedule is determined, a room will also need to be reserved for each meeting. This step can be done before the PSC members are selected or it can be done after members are selected in order to accommodate the individual members' schedules.

Expectations of PSC – (See "Overview" before Page 1)
Draft a Charter if you want one that is more specific than the 'Charter Example in Chapter 1 - (See Templates in the Appendices – All templates are also available in WORD Format)
Each Patient Safety Committee (PSC) needs to have a charter. The charter will help guide and scope the PSC's work. At a minimum, a charter should include information on the authority and scope of the work the PSC engages in, a confidentiality statement, sponsorship and oversight structure, a list of members, the meeting schedule/process and records and minutes. The Oncology Quality and Patient Safety Committee leadership are available to assist you and your team in drafting this document.

Ideally, a draft charter will be available to review during the first PSC meeting. Soliciting feedback from the PSC members before finalizing and approving the Charter during a PSC meeting is important to help engage the PSC members in their new role.

Prepare for First Meeting

The goal of this first Patient Safety Committee (PSC) meeting is to set up the PSC for success by laying a solid foundation for future meetings and the work of the Committee.

It must be made clear how serious St. Elizabeth Healthcare leadership is about these committee meetings, and how important it is that all members take this committee sincerely, or DO NOT participate at all. (See Page 9.)

Everyone will come to the first meeting with a different level of knowledge about patient safety. Therefore, it will also be important to spend time reviewing Patient Safety concepts. Consider having someone from the Oncology Quality and Patient Safety Steering Committee come to present concepts to your committee.

Agenda template – (See Appendix for all templates – Templates are also available in WORD Format)

Suggestions for first agenda – (See next sections for these suggestions)

Midas Reports

The Midas reports can drive the activities of the Patient Safety Committee (PSC). These reports may be able to show the committee safety related trends that the PSC can use to affect change to systems and processes and procedures. It is important that at least one member of the committee can run reports in Midas that show events related to a specific committee. The reports available in Midas should be reviewed to confirm that the correct reports are included for the team. **PLEASE NOTE**: These reports should be shown via overhead projectors, or screen monitors to the committee and NEVER printed out. The Midas system administrator can assist with existing reports and creating custom reports for the Team Leads.

Preparing for Future Patient Safety Committee Meetings

To continue building on the momentum you gained during the first Patient Safety Committee (PSC) meeting review the suggestions for future agenda items.

Suggestions for Patient Safety Committee Meeting Agendas

Suggested Standing Agenda Items for Every Meeting:

- Patient safety story – start every meeting with a patient safety story
  - These stories can be from a different healthcare system experience, or publication etc.
- Update from the previous Oncology Quality and Patient Safety Committee meeting
- Review Midas Report Trends
- Review high severity events from last month
- Walk-in Event descriptions from anyone, regardless if it was entered in Midas

Meeting #1: Laying the Foundation (60 minutes)

- Introductions
- Decide Committee meeting schedule
- Identify individual(s) to record minutes and process for approval
- Identify representative to attend the **OQPSC** monthly meetings.
- Other feedback mechanisms (dos and don'ts)
- Plan Kick-off with all identified members

Meeting #2: Getting Started – Tools

- Review the PSC Toolkit
    - Ensure knowledge of location of Toolkit and sections
- Review and update PSC Charter. The charter needs to be reviewed and approved yearly
- Confirm someone on the Committee is able to run reports in Midas and will be responsible for projecting Midas reports during the Committee meetings (Note: nothing can be printed.)

Meeting #3: Rolling Out the department Patient Safety Program

- Approve PSC charter
- Identify methods for informing staff about the PSC, the members and its work
- Ongoing Communication with staff

Meeting #4: Surfacing Issues to Address (May need to include someone from the OQPSC, or I.T. for help with data.)

- Review where to find data on patient safety events
    - Review Midas Reports
    - Review Data from Epic Reports If applicable (Note: on-screen only – NO PRINTING)
    - Most recent Patient Experience results if available
    - Discuss visible trends in the data if available
    - Review recent Midas reports and determine if a System Analysis should be performed. (Note: We use the term "System Analysis" in lieu of "Root Cause Analysis" due to legal requirements.

Meeting #5: Reviewing and Analyzing Events, Concerns and Trends

- Trend review and System improvements
- Prepare an update to the Oncology Quality and Patient Safety Committee
- Identifying big/important events for in depth analysis
- Causal Analysis Processes
- Action Plans and Follow-up

Suggestions for Patient Safety Committee Topics

- Improvement topics can always come from the Joint Commission's Annual Patient Safety Goals:
    - https://www.jointcommission.org/standards_information/npsgs.aspx

Suggestions for Patient Safety Committee Norms / Rules

New committees are encouraged to discuss and come to agreement on the rules that will govern their meetings and all actions taken by the team. Below are some ideas for team norms/rules of behavior. Please tailor the document to fit your Committee's needs.

Rule	Description	√	Modifications
Promptness	• The realities of patient schedules and clinic needs make it likely that some team members will be late to the meeting. However, team members will make every effort to be on time. • Meetings will start exactly on time.		
Attendance	• Attendance is expected unless the committee chair excuses a member. • At least half of the team members must be in attendance to hold the meeting.		
Agenda	• Every meeting will have a written agenda. An outcome of each meeting will be to establish an agenda for the next meeting.		
Minutes	• Every meeting will have a designated note-taker. The responsibility may rotate. • Minutes will be distributed to all team members at or before the next meeting.		
Participation	• Everyone is expected to participate actively during team meetings and in the work that takes place between meetings. • Team members will volunteer or agree to participate for "in-between meetings" work on a fair and equitable basis.		
Constructive Debate	• The ideas and input of everyone are important. Constructive debate will be encouraged and sought at appropriate times. • Team members agree to listen carefully until the speaker has finished his or her comments.		
Decision-Making	All major team decisions will be resolved by one of the following methods agreed upon by the team: • Consensus (All participants) • Voting (Core members only)		
Confidentiality	**All matters discussed within the team meetings should remain confidential unless there is a team decision that is appropriate to communicate outside of the room.** **Guidelines for Partial Confidentiality:** • **Members will honor any individual's request for confidentiality.** • **All topics are considered confidential unless the team decides otherwise.** • **The team should decide who may share information outside the committee.** • **When communicating information from the committee, team members will share general information and not specific references as to "who said what".** **Team members will not share specific information about patients or physicians/staff involved in their care.**		

CHAPTER 3 - - SUSTAINING A PATIENT SAFETY COMMITTEE

SUGGESTIONS FOR SUSTAINING A PATIENT SAFETY COMMITTEE

Now that you have created an ONCOLOGY PATIENT SAFETY COMMITTEE Safety Committee (PSC) and have been consistently reviewing and acting upon your patient safety data what do you do next? Below are suggestions on how to build upon the foundation you already have in place and advance your Patient Safety Committee.

Update Committee Charter

- Review the Committee's Charter on an annual basis to ensure it is current

Patient Safety Committee Charter Template – (at end of Chapter 2 and in Appendix)

Conduct Patient Safety Committee Walkarounds

- Make this a visible event where everyone knows why you are doing the walkaround

Consistently Communicate with the Medical Office/Area Staff

- Create and distribute a Committee newsletter
- Identify and executive feedback mechanisms
- Share Patient Safety Stories from the Medical Office/Area
- Share successes and outcomes of the PSC

Create a poster board that is accessible by all MOB staff that shows the status of meeting specific patient safety goals identified by the PSC. (I.e. list the number of days since the last fall)

Start the Day with a Patient Safety Story

Work with departments in the Medical Office/Area to start the day with a patient safety story.

Establish a Daily Safety Huddle in each Department

The next step is to work with departments who do not do daily huddles to start implementing one.

Provide Education and Training on Communication Methods to Oncology staff

- Safety Tools for Frontline Staff

Create a "Good Catch Program"

Create a "Good Catch Program" that rewards staff for reporting near-misses/potential errors that do not reach the patient – involve that staff member in finding a solution if appropriate; inform their manager, or perhaps include the story in a newsletter.

- Not capturing near misses, means you missed an opportunity to improve patient safety
- Associates should be publicly recognized during huddles and staff meetings for "Good Catches."

CHAPTER 4 - RECORD KEEPING

OVERVIEW OF RECORD KEEPING GUIDELINES

It is important that each ONCOLOGY PATIENT SAFETY COMMITTEE keep a record of its meetings and activities. The following pages are templates for your PSC to use or modify. If your PSC chooses to use another template, please make sure to include the following for all documents that could include confidential information:

1. A "confidential" label on each page

2. The following quality clause: This document is to be used for Oncology Quality and Patient Safety Committee and Risk Management purposes only. *This is a confidential document and is created as part of risk management activities. This document is not to be distributed, copied or published to anyone outside of the committee. Please securely destroy your copy after use or stored it in a secured manner.*

Templates:

Note about the templates: Each template has sections that look like "<<text>>". These are pieces of information that your PSC will need to fill in to tailor the template to your Medical Office/Area and/or meeting dates. The information to include is described in between the << >> symbols.

Patient Safety Committee Membership List

It is important to keep a current list of your Medical Office/Area's Patient Safety Committee members. The document should include names, titles, contact information, and identify the Chair(s).

Patient Safety Committee Meeting Sign-in Sheet

The Patient Safety Committee Meeting sign-in sheet also serves as an attestation of the confidentiality statement. Please keep a copy of each sign-in sheet for your records.

Patient Safety Committee Agenda

Prior to each meeting, it is suggested that the Committee creates a formal agenda and distributes it, so everyone knows the focus and tasks of the meeting. The Committee can decide how to set the agenda (ex. the Chair(s) set the agenda, the Committee members set the agenda at the end of each meeting, etc.). Example agenda items are listed below, and Committees are encouraged to start each meeting with a **Patient Safety story**.

LOCAL PATIENT SAFETY COMMITTEE MINUTES

Oncology Patient Safety Committee Minutes are structured to give a general overview of the Committee discussion with a focus on quality related patient safety issues. The Patient Safety Committee Minutes may identify opportunities for improvement. In addition, the Patient Safety Committee Minutes give a brief synopsis of decisions made and identify follow-up activities.

Minutes of Patient Safety Committee meetings may be reviewed for regulatory requirements.

Minutes shall:

- Be recorded during each Patient Safety Committee meeting for subsequent review and approval by the Committee members.
- Contain a general summary of information related to process of care/quality related patient safety events discussed at the meeting. Specific identifiers (i.e., names, patient medical numbers, etc.) shall not be included in the minutes.
- Identify the events/trends reviewed and discussed.
- Be reviewed by committee members during the Patient Safety Committee Meeting and approve with or without noted changes.
- Be maintained confidential in a secured folder, binder or electronically (as long as the patient has been deidentified).
- Be returned at the end of the meeting.
- Include the following information:
    - Members and guests present
    - Date, time and location of meeting
    - Discussion/agenda items, including any barriers to completing the identified actions
    - Decisions made, follow-up actions to be taken and responsible party
    - Name of person submitting minutes
    - Record of approval for the last meeting's minutes
    - **The following statement:**

      "This document is to be used for St. Elizabeth Healthcare Oncology Patient Safety Committee and Risk Management purposes only. ***This is a confidential document and is created as part of risk management activities. This document is not to be distributed, copied or published to anyone outside of the committee. Please securely destroy your copy after use or stored it in a secured manner."***

- **Minutes may be sent electronically to the committee members for review prior to meetings with the above confidentiality statement in the email: HOWEVER, THERE MUST NEVER BE PATIENT IDENTIFYING INFORMATION, INCLUDING MRN NUMBERS, OR CSN NUMBERS, ETC. IN ANY EMAIL CORRESPONDENCE.**

- **Also, always add "[SECURE]" at the beginning or end of every Subject line. If you are unsure about how to do this, please ask and DO NOT send the email.**

Confidentiality Statement Below must be included on any email documentation from the PSC:

By receiving and opening the following attachments, I acknowledge that I am an authorized member or guest of the St. Elizabeth Healthcare Oncology Patient Safety Committee, and as such, am subject to the following terms and conditions:

- I agree to respect and maintain the confidentiality of all discussions, records and information generated in connection with the meeting and agree not to disclose such information.
- I agree NOT to forward this email or its contents without written authorization from the originator.
- I agree to use the information contained within this email for the purposes of the ONCOLOGY PATIENT SAFETY COMMITTEE Improvement and Prevention activities and to delete this email after its use.
- **Minutes MUST NOT include any PHI**

TEMPLATE – LOCATED IN THE APPENDICES

Patient Safety Committee Membership List

<<Name of Oncology Area>>

Membership List Last Updated: <<DATE>>

ST. Elizabeth Healthcare Oncology Patient Safety Committee - Confidential – Do Not Distribute

Name (as on email)	Position/Title	Department	Office Phone

TEMPLATE – LOCATED IN THE APPENDICES

Patient Safety Committee Sign-In Sheet

<<Name of Oncology Committee>>

Date of Meeting: <<DATE>>

My signature below acknowledges that I am an authorized member of the St. Elizabeth Healthcare Oncology Patient Safety Committee

<<Name of Oncology Area>> Patient Safety Committee and I am subject to the following terms and conditions:

- I agree to respect and maintain the confidentiality of all discussions, records and information generated in connection with the meeting and agree not to disclose such information.
- I acknowledge and agree that I will not testify or provide any written statements or information of any kind relating to the meeting in any discovery process or any administrative court hearing or proceeding unless compelled to do so by a court of competent jurisdiction.
- I agree to raise all legal defenses, privileges and immunities which may be available by law to preserve confidentiality of and to prevent the disclosure of all records and information generated in connection with the meeting.

Template Last Updated:

Name (Please Print)	Department	Initials

TEMPLATE – LOCATED IN THE APPENDICES

Patient Safety Committee Agenda

<<Name of Oncology / Area>>

Meeting Date:
Meeting Time:
Meeting Location:

Chair(s): Name, Title
Note Taker: Name, Title

Time	Topic	Details	Owner
	Patient Safety Story	Every PSC Meeting Have a member share a Patient Safety Story	
	Update from Regional PSC meeting/huddle	Every PSC Meeting Proved an update on the last Regional PSC meeting and/or huddle	
	Midas Report	At least quarterly Review the latest Midas Report and choose at least one to task a member to do a "System Review" on that event and present at the next meeting.	
Next meeting: <<Date>> from <<Time>> in the <<Room>>			

Do Not Distribute: This document contains Quality, Patient Safety and Risk Management Information. This information is to be used for St. Elizabeth Healthcare Oncology Patient Safety Committee purposes only. *(This is a confidential document and is created as part of risk management activities. This document is not to be distributed, copied or published to anyone outside of the committee. Please securely destroy your copy after use or stored it in a secured manner.)*

TEMPLATE – LOCATED IN THE APPENDICES

Patient Safety Committee Minutes

<<Name of Oncology Committee>>

Meeting Date:

Chair(s): Name, Title
Note Taker: Name, Title

Topic	Details/Discussion	Action/Follow-up	Owner
Next meeting: <<Date>> from <<Time>> in the <<Room>>.			

Do Not Distribute: This document contains Quality, Patient Safety and Risk Management Information. This information is to be used for St. Elizabeth Healthcare Oncology Patient Safety Committee purposes only. *(This is a confidential document and is created as part of risk management activities. This document is not to be distributed, copied or published to anyone outside of the committee. Please securely destroy your copy after use or stored it in a secured manner.)*

CHAPTER 5 - - ANALYSIS OF A SAFETY EVENT

Once the data is gathered or the safety issue is identified, the Patient Safety Committee is instrumental in analyzing the information to make the changes necessary to prevent that event from occurring again.

Additional tools that can be used to analyze an event and conduct a System Review to Improve a Process are as follows:

- Just Culture Algorithm
- Swiss Cheese Model
- 5-Whys
- Fishbone Diagram

JUST CULTURE ALGORITHM

The Just Culture Algorithm

Purpose: The purpose of this document is to provide insight and guidance regarding our process for allocating accountability for adverse event. This algorithm should be used to determine what the cause is by the system and what is caused by the human interaction. It is to be used following a thorough analysis of an event which reveals if an individual *may* hold causal responsibility. The process leads us to fair and just management of the critical elements within our control: Resulting in designing safe systems and helping people make safe choices.

Expectations of Management in a Just Culture:

- Create an open learning environment
- Work with staff to design systems that reduce the rate of human error and at-risk actions, or mitigate their effects
- Hold staff accountable for reckless actions and/or repetitive human errors and at-risk actions

Role of Staff in Just Culture:

- Look for risks in our systems and choices
- Report hazards and adverse events
- Participate in event analysis – being open and honest about what happened

Definitions:

System Induced Human Error: The product of the system's current design, involving inadvertent or unintentional action that causes, or could have caused, an undesirable outcome.

At Risk Action: A choice that increases risk where risk is not recognized or is mistakenly believed to be justified.

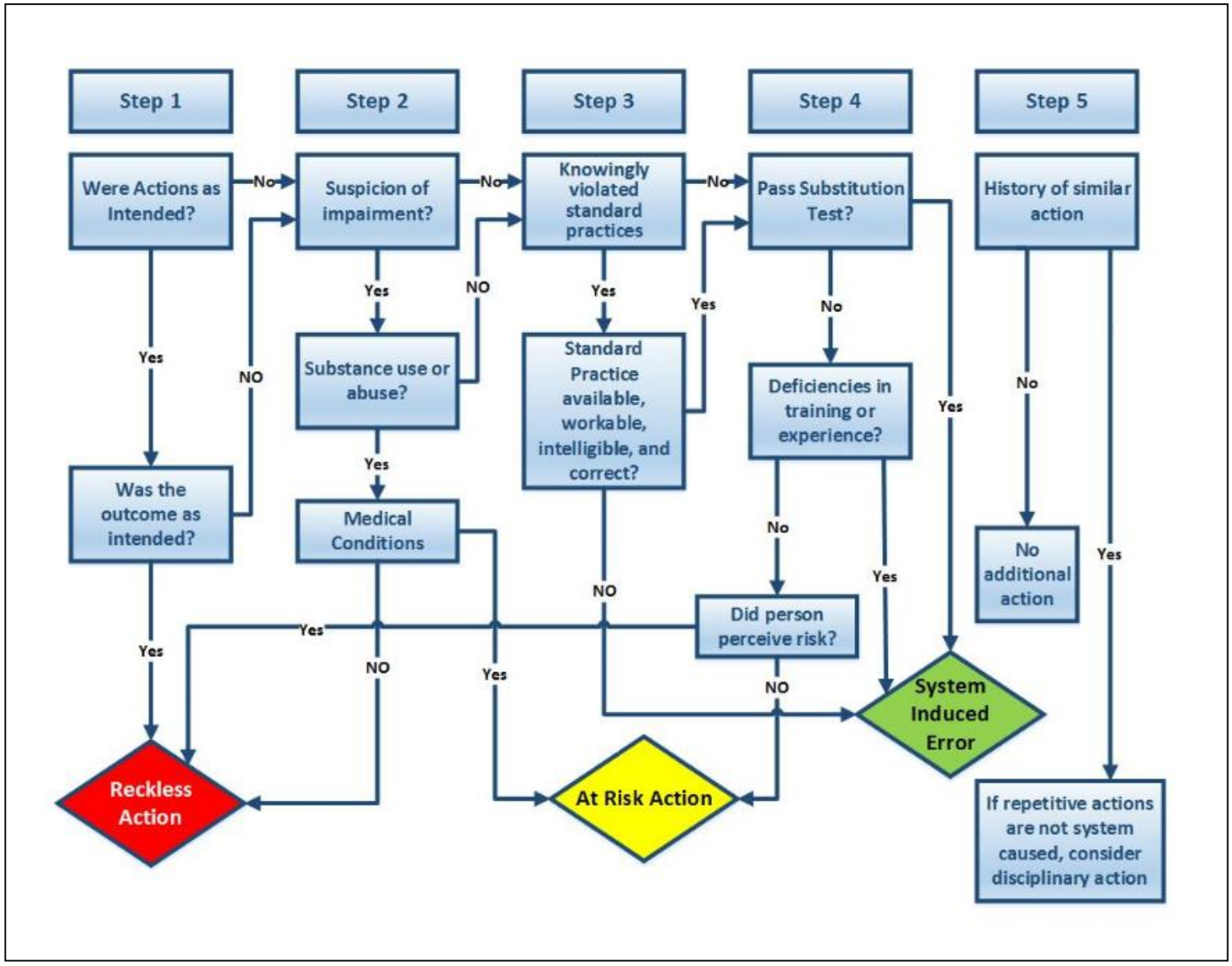
Reckless Action: A choice to consciously disregard a substantial and unjustifiable risk.

Just Culture: A culture where team members share information, understand the systemic factors that shape their behavior, and have a shared understanding of the line between acceptable and unacceptable actions. Leaders understand that advances in safety and performance depend on the ability to learn from mistakes and are grounded in the belief that most errors are multifactorial, not the fault of any one person. Leaders fairly and equitably apply a just culture protocol that draws the line between system induced (human) errors, at risk actions, and reckless actions.

Just Culture Algorithm: An agreed set of principles for drawing the line between acceptable and unacceptable actions that also provides insight regarding management of related risks through development of effective solutions for preventing future occurrence of similar actions. The outcome severity associated with the error has no impact on the Just Culture Algorithm.

Substitution Test: Also known as the "reasonable person test", this test asks the question “Could another similarly trained peer draw the same conclusions, or make the same choices, given the context and facts available at the time?”

System: The Institute of Medicine (IOM) defines a system as a "set of interdependent elements interacting to achieve a common aim". These elements may be both human (communication, teamwork), and non-human (work environment, equipment, technologies, policies and procedures, delivery systems etc.) The IOM goes on to say that “Safety does not reside in a person, device, or department, but emerges from the interactions of components of the system."


Step 1
Step 2
Step 3
Step 4
Step 5
Were Actions as Intended?
No
Suspicion of impairment?
No
Knowingly violated standard practices
No
Pass Substitution Test?
History of similar action
Yes
NO
Yes
NO
Yes
Yes
No
No
Substance use or abuse?
Standard Practice available, workable, intelligible, and correct?
Deficiencies in training or experience?
Was the outcome as intended?
Yes
Medical Conditions
No additional action
Yes
Yes
NO
Yes
NO
Yes
Did person perceive risk?
Yes
NO
NO
Yes
System Induced Error
Reckless Action
At Risk Action
If repetitive actions are not system caused, consider disciplinary action

JUST CULTURE ALGORITHM INSTRUCTIONS

Instructions for using the Just Culture Algorithm: Complete Steps 1-4, as needed, to identify either System Induced Human Error, At Risk Action, or Reckless Action (and review corresponding management practices), then move to Step 5 to identify and manage Repetitive Actions.

Step 1

The first line of questioning in the model looks at intent, and asks "**Were the actions as intended?"** In other words, was the action an omission, or deliberate? If the answer to this is "yes" the question, then becomes **"Was the outcome as intended?"** This question is to determine if the person acted knowing the consequences of his/her action. If the answer to both questions are "yes" then it is considered a "Reckless Action".

> **Examples: "**Reckless Actions" include sabotage, malevolent damage, patient abuse, and fraud (which are extremely rare, but need to be monitored.). Clinical examples of this would be an individual who knowingly gives a patient a lethal dose of a medication with the intent of harming the patient, or an individual who intentionally fraudulently signs another person's name as having completed the double check of a medication when in fact that person had not been involved in the double check. A non-clinical example would be if a staff member calls in sick on the day of a mandatory meeting, and you find they were at Disneyland, based upon their social media posts. (EXTREMELY Rare, but possible.)
>
> **Manager Actions:** Reckless Actions in which the consequence is intended should be handled according to organizational policies and should first be communicated with **Risk Management.**

Step 2

If the answer to the question related to intent is "no" the next question to ask is **"Was substance use or abuse involved?"** This question is asked to determine if the person was under the influence at the time the incident occurred. If the answer to this is "yes" it is necessary to determine if the person was taking drugs for **a medical condition.** If the person was not taking the drugs for a medical condition, the action is considered "Reckless". If the person was taking the drugs for a medical condition, the action is considered "At Risk".

> **Manager Actions:** Substance abuse should be handled according to organizational policies (e.g. referral to Human Resources). If the person was taking drugs for a medical condition, organizational policies may require him/her to seek treatment from a qualified provider.

Step 3

If the person was **not** under the influence of drugs or alcohol the question to be asked is **"Did the individual knowingly violate standard operating procedures or practices?"** If the answer to this question in "no," the process continues to Step 4**.** If the answer is "yes", the next question is **"Were the procedures/practices available, workable, intelligible and correct?"** If the answer to this question is "no," it is considered a "system induced human error". If the answer to this question is "yes", the process continues to Step 4.

> **Manager Actions:** When System Induced Human Errors are detected, it is appropriate to both console the staff and conduct an analysis to identify and define systems issues (and develop sustainable action plans to mediate the identified systems and process issues).

Step 4

When indicated, the next step is to utilize the **"substitution test".** Also known as the "reasonable person test", this test asks the question **"Could another similarly trained peer draw the same conclusions, or make the same choices, given the context and facts available at the time?"** The substitution test should be presented in the context of the situation in which the event occurred but de-identified to remove personal bias. If the answer is "yes", the substitution test is passed, and this is considered a "system-induced human error" issue. If the answer is "no", the substitution test is not passed, and it is necessary to ask the question "**Were there deficiencies in training or experience?"** If the answer is "yes," this would be considered a "systems induced human error" issue. If the answer to this is "no," then ask, "**Did person perceive the risk**?", if "yes" then it would be considered a "reckless action", if no, then it would be considered an "at risk action". In all instances, Step 5 should also be completed.

> **Examples:** A surgeon does not mark the surgical site prior to surgery. The event analysis reveals that the surgeon knowingly violated this standard practice and that there were available, workable, intelligible and correct procedures available. Furthermore, this did not pass the Substitution Test and there were no deficiencies in training or experience. When asked, the surgeon explained that he/she perceived no risk, explaining that they had never made a wrong site error and believed that there is equal risk of marking the incorrect site. In this case, there was no perceived risk, and it would be considered an "at risk action". If, under the same circumstances, the surgeon stated that he/she *did* understand (perceive) the risk of failing to mark the surgical site and chose to go forward with the surgery, it would be considered "reckless action".
>
> **Manager Actions:** If the substitution test is passed (system induced human error), the manager must take steps to fully identify the system and process failures(s) and implement sustainable remedial actions to prevent recurrence. If the substitution test is failed and deficiencies in training or experience are identified (system induced human error), the manager must take remedial action to eliminate those deficiencies. If the substitution test fails due to unperceived risks (at risk action), the manager should coach the individual and take remedial action to mitigate future risk. If the substitution test fails due to perceived risks (reckless action), the manager should take remedial action to mitigate future risk and consider disciplinary action.

Step 5

After Steps 1-4 have determined an action to be either a System Induced Human Error, At Risk Action or Reckless Action, the issue of repetition should be considered by asking the question "**Does this individual have a history of similar action**?" This important question should be considered separate from the event that is being addressed. If a history of unsafe acts is **not** identified, no further action is needed. If a history of unsafe acts **is** identified, and the causes of these actions a process, or system issue, disciplinary action may be considered.

> **Manager Actions:** In managing individuals who have a history of unsafe acts it is important to ensure that the source of these acts does not reside within the system. If the acts have been determined to be systems issues, they should be identified and remediated. If the unsafe acts do not relate to the system, counseling may be taken to ensure that the individual addresses personal performance shaping factors and is able to make better choices. In some cases, reassignment or further disciplinary steps may be indicated.

Manager Notes: Individuals involved in adverse events may be devastated by the experience, particularly if harm has occurred to the patient. The manager should console the individual and refer them to EAP or other programs as appropriate. In addition, the following guide should be used to manage each of the 3 types of actions identified in Steps 1-4 of the algorithm, as well as cases of repetitive actions identified in Step 5 of the algorithm:

1. **System Induced Human Error –** Console the individual and manage the system

   Individual:
   - Console individual
   - Discuss recommendations for remedial action to prevent recurrence

   Systems:
   - Ensure that an analysis is conducted to identify and define systems issues and develop and implement sustainable action plans. Examples of potential actions include the following:
     - safety nets to "catch" the error before it impacts the outcome
     - checklists to prevent reliance on human memory
   - Share learnings with colleagues and other appropriate parties

2. **At Risk Action** – Coach the individual and remediate risks

   Individual:
   - Coach individual using supportive discussion, role-modeling, mentoring, observations and real-time feedback regarding choices and actions

   Systems:
   - Ensure that an analysis is conducted to identify and define systems issues and develop and implement sustainable action plans. Examples of potential actions include the following:
     - remove sources of drift
     - remove incentives for at-risk actions
     - create incentives for safe actions
     - increase situational awareness
     - decrease tolerance for taking risks
     - make it easy to do the right thing and harder to do the wrong thing
   - Share learnings with colleagues and other appropriate parties

3. **Reckless Action** – Remedial and/or disciplinary measures

   Individual:

   - Handle according to organizational policies and with involvement of appropriate parties (i.e. senior leadership, human resources, labor relations, security, and, if appropriate, law enforcement

   - Intentionally malicious actions that do not result in harm or damages due to intervention or luck should be dealt with in the manner stated above (outcome should not be a determining factor)

   Systems: there may be instances where systems related issues exist in parallel with Reckless Actions. In these cases, an analysis should be conducted to identify and define systems issues and develop and implement sustainable action plans.

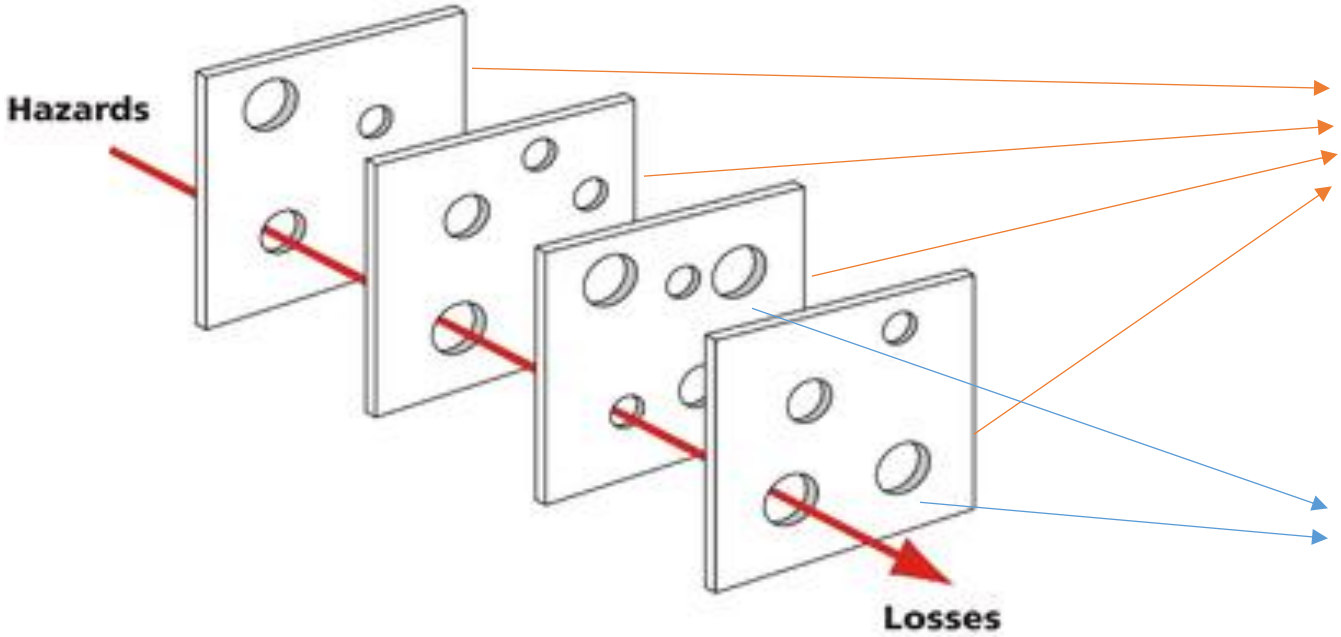
4. **Repetitive actions –** If the causes of the repetitive actions do not reside within the system, it may be necessary consider disciplinary action to best serve organizational values and improve outcomes. Follow organizational policies, engage appropriate parties, and consider the following:

   a. **Counsel individual** – Put individual on notice that performance is unacceptable, and assist them in making better choices
   b. **Reassignment** – Assist individual in finding a better fit for their skills and talents
   c. **Termination** – A last resort

HIGH RELIABILITY ORGANIZATION PRINCIPLE EXAMPLE

THE SWISS CHEESE MODEL

The Swiss cheese model of accident causation illustrates that, although many layers of defense lie between hazards and accidents, there are flaws in each layer that, if aligned, can allow the accident to occur.



Layers of Defense Include:

- Equipment/Building
- Processes and Procedures
- Technology
- People

The Flaws in the Layers of Defense:

- Active Errors
- Latent Weaknesses

Swiss Cheese Model Explained:

The **Layers of Defense** in this example could be:	The **Flaws in the Layers of Defense** could be:
1. The physician entering the order (People) 2. The electronic medical record where the order was entered. (Technology) 3. The pharmacist counseling the patient on the new prescription. (Process) 4. The patient. (People)	1. Physician self-checking (People) 2. The EMR not having tall man lettering in the system for this sound alike medication. (Technology) 3. The counseling session being rushed. (Process) 4. The patient not hearing the pharmacist due to impaired hearing and the location of the counseling being too open. (Building)

5 WHYS OVERVIEW

5-Whys

The 5-Whys is a simple tool that can help conduct a System Review to Improve a Process. Asking the 5-Whys allows teams to move beyond obvious answers and reflect on less obvious explanations or causes.

Step-by-Step Instructions

1. State the problem.
2. Start asking "why" related to the problem.
3. Ask as many whys as you need to in order to get insight at a level that can be addressed (asking five times is typical). You will know you have reached your final "why" because it does not make logical sense to ask why again.

Caution

- If your last answer is something you can't control, go back up 1 why to the previous answer.
- **The final answer cannot be because of a person. Why would a reasonable person make the choices that person did to lead to the problem? Could another person make the same choices and have the same problem?**

FISHBONE DIAGRAM

Cause and Effect Diagram

A cause and effect diagram, also known as an Ishikawa or "fishbone" diagram, is a graphic tool used to explore and display the possible causes of a certain effect. Use the classic fishbone diagram when causes group naturally under the categories of Materials, Methods, Equipment, Environment, and People. Use a process-type cause and effect diagram to show causes of problems at each step in the process.

Cause and effect diagrams have a variety of benefits:

- It helps teams understand that there are many causes that contribute to an effect.
- It graphically displays the relationship of the causes to the effect and to each other.
- It helps to identify areas for improvement.

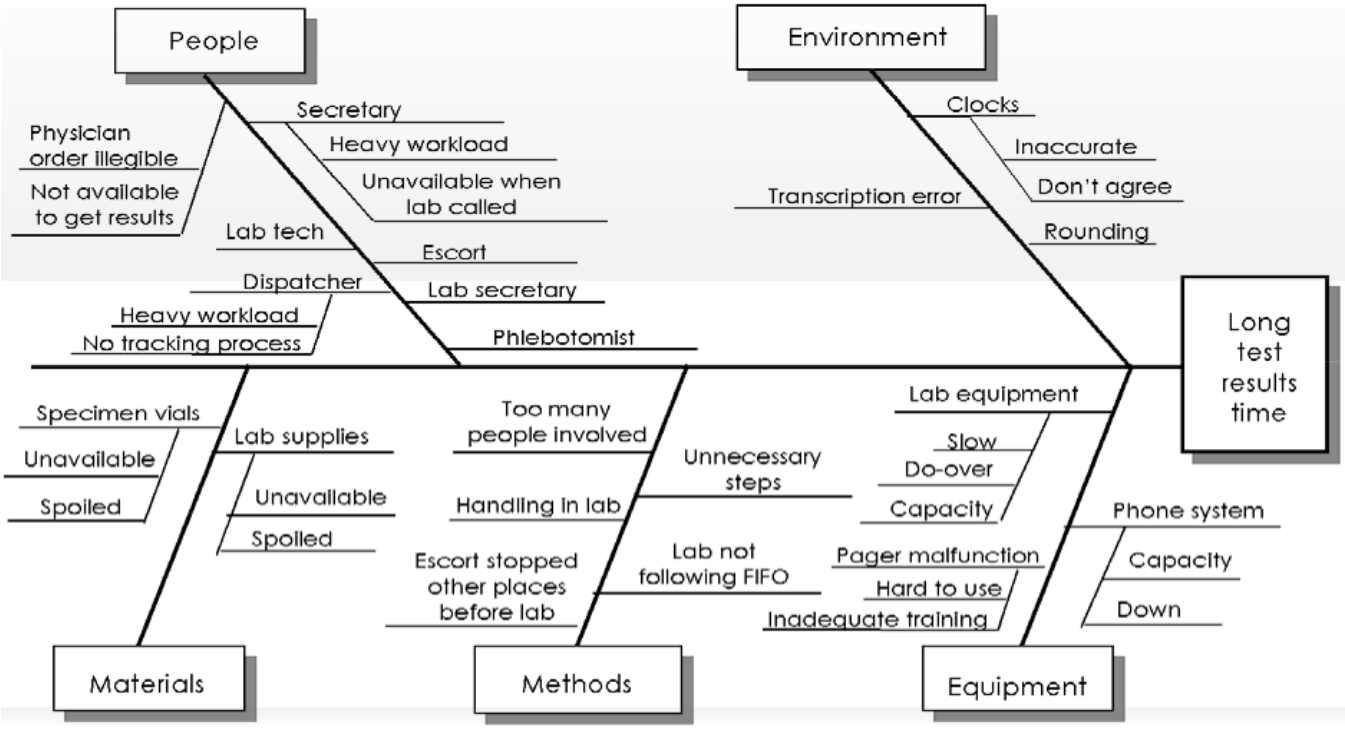
This tool contains:

- Directions for making a Cause and Effect Diagram
- Cause and Effect Diagram: "Fishbone"
- Cause and Effect Diagram: Process-Type

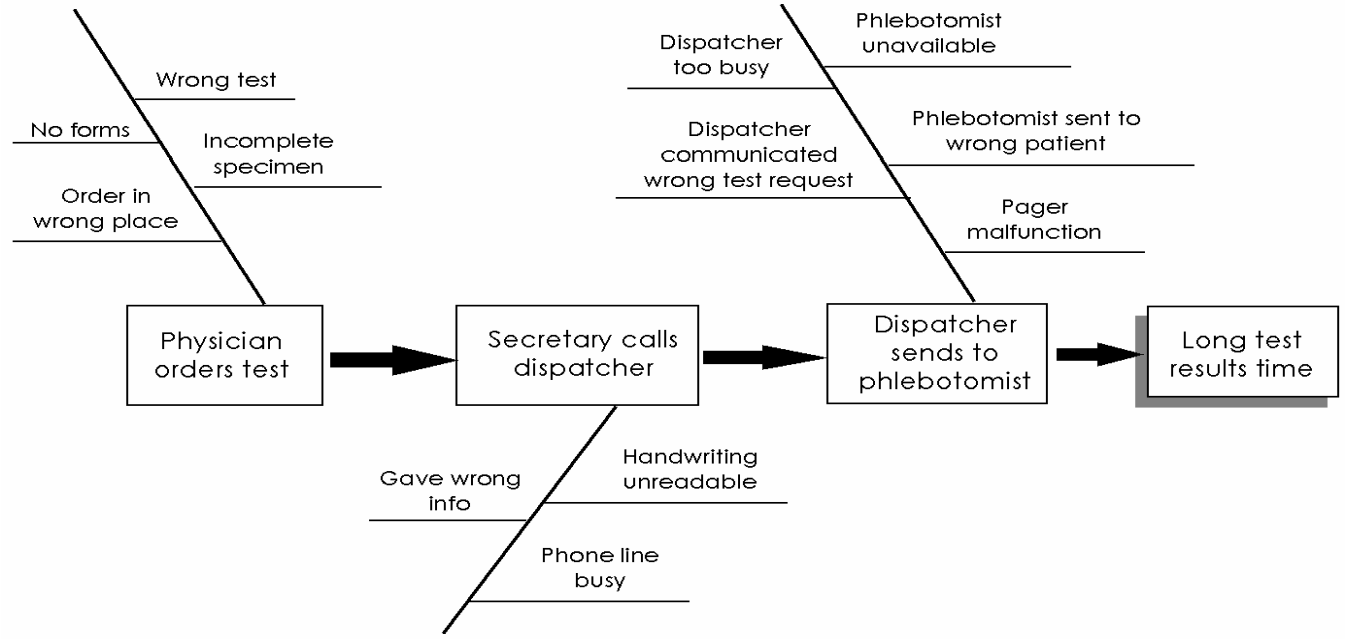
Directions

1. Write the effect in a box on the right-hand side of the page.
2. Draw a horizontal line to the left of the effect.
3. Decide on the categories of causes for the effect. Useful categories of causes in a classic fishbone diagram include Materials, Methods, Equipment, Environment, and People. Another way to think of categories is in terms of causes at each major step in the process.
4. Draw diagonal lines above and below the horizontal line (these are the "fishbones"), and label with the categories you have chosen.
5. Generate a list of causes for each category.
6. List the causes on each fishbone, drawing branch bones to show relationships among the causes.
7. Develop the causes by asking "Why?" until you have reached a useful level of detail—that is, when the cause is specific enough to be able to test a change and measure its effects

Cause and Effect Diagram: "Fishbone"



Cause and Effect Diagram: Process-Type



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APPENDICES

Following Pages

Template Last Updated: 10/26/2019

TEMPLATE – AGENDA

Patient Safety Committee Agenda

<<Name of Medical Office Building/Area>>

Meeting Date:
Meeting Time:
Meeting Location:

Chair(s): Name, Title
Note Taker: Name, Title

Time	Topic	Details	Owner
	Patient Safety Story	Every PSC Meeting Have a member share a Patient Safety Story	
	Update from Regional PSC meeting/huddle	Every PSC Meeting Proved an update on the last Regional PSC meeting and/or huddle	
	Midas Report	At least quarterly Review the latest Midas Report	
Next meeting: <<Date>> from <<Time>> in the <<Room>>			

Do Not Distribute: This document contains Quality, Patient Safety and Risk Management Information. This information is to be used for St. Elizabeth Healthcare Oncology Patient Safety Committee purposes only. ***(This is a confidential document and is created as part of risk management activities. This document is not to be distributed, copied or published to anyone outside of the committee. Please securely destroy your copy after use or stored it in a secured manner.)***

TEMPLATE – SIGN-IN SHEET

Radiation Patient Safety Committee Sign-In Sheet

Date of Meeting:

My signature below acknowledges that I am an authorized member of the St. Elizabeth Healthcare Oncology Patient Safety Committee

Radiation Patient Safety Committee and I am subject to the following terms and conditions:

- I agree to respect and maintain the confidentiality of all discussions, records and information generated in connection with the meeting and agree not to disclose such information.
- I acknowledge and agree that I will not testify or provide any written statements or information of any kind relating to the meeting in any discovery process or any administrative court hearing or proceeding unless compelled to do so by a court of competent jurisdiction.
- I agree to raise all legal defenses, privileges and immunities which may be available by law to preserve confidentiality of and to prevent the disclosure of all records and information generated in connection with the meeting.

Template Last Updated:

Name (Please Print)	Department	Initials

Date Updated: 10/26/2019

TEMPLATE – PATIENT SAFETY COMMITTEE CHARTER

Radiation Patient Safety Committee Charter

Mission/Vision

(Highlight the Committee's overall mission/vision/purpose. Remember the patient/member.)

Purpose/Objectives

(Describe the purpose of the Committee and outline its objectives.)

Scope

In Scope	Out of Scope

Sponsorship Structure and Oversight

Sponsorship Structure
(Topics to include: a diagram that includes committee support, Committee Chairs, and Committee sponsors)

Oversight Structure
(Topics to include: a diagram of each layer of oversight, including who the Committee oversees and who has oversight of the Committee; this should not necessarily include the actual work being done)

Committee Membership
(Topics to include how are members identified; who are the committee members and Chair(s); whether ad hoc members will be added and when; whether members are term limited)

Meeting Schedule/Meeting Process
(Topics to include how meetings will be scheduled; at a minimum, how often meetings will be held)

Records and Minutes
(Topics to include will minutes be documented and what information will be included; will minutes be approved and if so, how will approval occur; what department/who will maintain the minutes)

TEMPLATE – MEMBERSHIP LIST

Radiation Patient Safety Committee Membership List

Membership List Last Updated: <<DATE>>

ST. Elizabeth Healthcare Oncology Patient Safety Committee - **Confidential – Do Not Distribute**

Name (as on email)	Position/Title	Department	Office Phone

Revisions Notes:

Revision A – Original Document

Revision B – 10/26/19

1.) Page 2 – Chapter 1 – renamed to “Charter Example”
2.) Page 3 - Replaced “Joe Rectenwald” with “Risk Management”
3.) Table of Contents Page Updated with new page numbers.
4.) Removed: “Midas RDE Entry Instructions”
5.) Renumbered all Pages
6.) Corrected two typos

Revision C – 11/04/19

1.) Page 1 grammar and word changes
2.) Page 2 changing OQPSSC to OQPSC (Without the word “Steering”)
3.) Page 3 Typos and Font Changes
4.) Page 5 Removed the word “Steering”
5.) Page 7 grammar corrections and removed the word “Steering” and the “S” from OQPSSC.
6.) Page 8 – Same as Page 7
7.) Page 10 – grammar corrections
8.) Page 12 – Removed text from old PSC Tool kit: (i.e. “Medical Offices”)