

## Instructions

It is important for each hospital or ambulatory site in a multihospital or ambulatory system to complete the self assessment individually.

### 1. Establish an interdisciplinary team consisting of, or similar to, the following:

- Senior administration representative
- Chief medical officer
- Nurse executive
- Director of pharmacy
- Chief information officer
- Clinical information technology specialist
- Medication safety officer/manager
- Risk management and quality improvement professionals
- At least two staff nurses working in oncology care areas
- At least two staff oncology pharmacists (one clinical and one distribution)
- At least one active oncology staff physician.

It is helpful to appoint a team leader to coordinate the process. Other practitioners and staff (e.g., biomedical personnel, certified nurse practitioners, receptionists) may need to join the core team for evaluation of certain sections of the self assessment.

Your team should be provided with sufficient time to complete the self assessment and be charged with the responsibility to evaluate, accurately and honestly, the current status of medication practices as they relate to oncology in your facility. Because medication use is a complex, interdisciplinary process, the value and accuracy of the self assessment is significantly reduced if it is completed by a single individual or discipline involved in oncology medication use. Based on participant feedback from prior self assessments, we anticipate that it will take three team meetings of approximately 1 to 2 hours each to complete this self assessment.

### 2. Read and review the self assessment in its entirety, including the instructions, Key Definitions, and Frequently Asked Questions (FAQs) before beginning the assessment process.

The team leader should provide copies of the self assessment tool, FAQs and Key Definitions to all team members for review before the first meeting. In the electronic version, FAQ information and Key Definitions can be accessed by hovering over the FAQ icon or the defined item (shown in **SMALL CAPITAL LETTERS**).

### 3. Verify your demographic information.

Before the first team meeting, the team leader should review and verify the responses in the demographics section with the administration of the hospital/ambulatory organization/practice setting as discussed in the FAQs.

### 4. Convene the team.

During the assessment meetings, ensure that each team member can view either a hardcopy or electronic version of the self assessment. There are a couple of options for completing the assessment:

- **Option 1:** Print hardcopies of the self assessment to share with team members, manually complete the demographic information, and fill in your choice (A through E, or Not Applicable [N/A]) for each self assessment item. Once completed, submit your information online at: <http://mssa.ismp-canada.org/oncology>.
- **Option 2:** Use the online self assessment form to view at team meetings, complete the demographic information, and enter your choice (A through E, or Not Applicable [N/A]) for each self assessment item, saving your username/password-protected document at the end of each meeting. (**Please see Step 8 for information regarding accessing the online self assessment form and obtaining a username and password.**)

### 5. Discuss each core characteristic and evaluate the organization's/practice setting's current success with implementing the self assessment items within that core.

## Instructions (continued)

As necessary, investigate and verify the level of implementation with other healthcare practitioners and staff outside your core assessment team. When a consensus on the level of implementation for each self assessment item has been reached, select the appropriate checkbox (A through E, or Not Applicable [N/A]), using the following scoring key and guidelines:

### Scoring Key

- A.** There has been no activity to implement this item.
- B.** This item has been formally discussed and considered, but it has not been implemented.
- C.** This item has been partially implemented in the organization for some or all areas, patients, drugs, and/or staff.
- D.** This item is fully implemented in the organization for some or all areas, patients, drugs, and/or staff.
- E.** This item is fully implemented throughout the organization for all patients, drugs, and/or staff.
- N/A.** (Not applicable) will be available as an option for specific questions.

Organizations may want to consider assigning an individual to record any discussion generated around each self assessment item and the rationale behind the selected choice. This information, meant for internal use only, can assist the team when reviewing scores for individual items or reassessing your organization at a later date and will provide insight into why the choice selected for each self assessment item was chosen.

### Scoring Guidelines

- **For all self assessment items:** Self assessment items refer to chemotherapy/biotherapy medications prescribed, dispensed, and administered to *all* inpatients and outpatients for both the treatment of oncology and non-oncology disease processes (e.g., methotrexate for rheumatoid arthritis or psoriasis).
- **For all self assessment items:** Choice of E (full implementation) is appropriate only if all components are present in *all* areas of the organization, for all patients, all medications, and followed by all staff. If only one or some of

the components of the item have been fully implemented in only some or all areas of the organization, your self assessment choice should be D.

- **For self assessment items with an option of “Not Applicable” (N/A):** Select “Not Applicable” (N/A) only if the item does not correspond to any services you provide in your organization/ practice setting. N/A responses are scored the same as answering B (This item has been formally discussed and considered, but it has not been implemented).

### 6. Repeat the process outlined in Step 5 for all self assessment items.

- 7. If you have questions:** Refer to the FAQs and Key Definitions – these are directly linked in the online form and identified in the PDF version via an **FAQ** icon or use of **SMALL CAPITALS FONT** for the Key Definitions.

For additional questions, contact ISMP at [oncselfassessment@ismp.org](mailto:oncselfassessment@ismp.org) or call 001 215 947 7797 from 9 am – 5 pm (Eastern Daylight-Saving Time). If you are experiencing technical difficulties with the online assessment portal, contact ISMP Canada at: [mssa@ismp-canada.org](mailto:mssa@ismp-canada.org).

- 8. To submit your final completed assessment or to use Option 2 to complete the assessment,** go to <http://mssa.ismp-canada.org/oncology>, and click on the link to register.

*See the next section, Instructions for Entering and Submitting Information to ISMP/ISMP Canada, for further information about obtaining a username and password, entering your information, and submitting your completed assessment.*

- 9.** Once you have entered and submitted your information online, **you will be prompted to print a report which will summarize your results.** This is explained in detail in the next section.

## Instructions for Entering and Submitting Information to ISMP/ISMP Canada

### 1. To access the oncology self assessment webpage.

From any computer with Internet capability, go to: <http://mssa.ismp-canada.org/oncology> to access the **2012 ISMP International Medication Safety Self Assessment® for Oncology** webpage. This webpage will provide all the links you need to print and view the assessment, register, complete the self assessment, submit your information, and view your results.

### 2. To register.

Once the assessment webpage has been accessed, you will see two blue boxes at the top of the page; one for “New User Registration” and the other for “Existing User Login.” To register, click on the “New User Registration” box to open the registration page. You will be prompted to select a username and password. You then have the option to provide an email address to be used only if necessary for password recovery. You have a further option to provide your full contact information so that information can be retrieved by ISMP in the event that you lose your login details. If you have not provided your email address or full contact information, ensure you record your username and password, and keep them in a safe place. Your username/password is required to:

- Enter your information into the online self assessment form;
- Save your entered information and return to the online form at a later time to complete the assessment;
- Submit your completed self assessment to ISMP; and
- View and print a report of your self assessment with scoring once it has been submitted.

### 3. To enter assessment information.

- **Entering data:** Once you are logged in, you can start entering data and saving your responses.

You can maneuver through the tool by using the dark blue tabs at the top of the screen that relate to each section (Demographics, I, II, III, etc.). You can also move from section to section by using the “Next Section” or “Previous Section” tabs that appear at the bottom right of the screen.

- **Saving data:** You can click on the “Save” button at the bottom left of the screen any time after data has been entered. You can always go back and edit your responses and click the save button again to update your information. To exit the online form, click on the “Logout” button found at the top right of the page. In order to return to your saved information, you will need to go to the homepage and click the “Existing User Login” box, and then enter your username/password.
- **Check MSSA for Errors:** You can click on this button (located near the “Save” button at the bottom left) at any time to see which items in the demographics section have not been answered or which other sections are incomplete. If all the items in the section have been answered, a green check mark will appear next to the section tab at the top of the screen.

### 4. To submit your completed assessment.

Once all the items have been answered and saved, a message box will pop up telling you, “The MSSA is now complete. Do you want to submit the results to ISMP Canada?” You can click OK to submit your self assessment responses or Cancel to go back to the tool.

- **If you select OK:** Your responses will be submitted – you will NOT be able to make any changes to your information if you select OK.
- **If you select Cancel:** Your responses will be saved, but you can still go back and make changes. You can even log out and log back in to make changes.
- If you saved your changes and did not submit your results, the Check MSSA for Errors button will say

## Instructions for Entering and Submitting Information to ISMP/ISMP Canada (continued)

Submit MSSA results unless you make changes. If you do not make any changes, click on that button to submit your responses. If you make changes and save them, the pop up box will come up again telling you the assessment is complete and will ask if you want to submit your results.

### 5. To generate your report.

Once you have submitted your completed self assessment, a message box will appear stating that the MSSA has been finalized. At this point you can view your responses but you will not be able to make any changes.

You will be prompted to print a report of your submitted self assessment with your answers and numerical scores for each of the self assessment items, subtotals for each of the core characteristics and key elements, and a total score for the entire self assessment. Note that the scored report will be approximately 20 pages in length.

**If you have not supplied your email or full contact information to obtain a lost or forgotten username/password, ensure that this report and your username/password are maintained in a safe location so you can compare your organization's/ practice setting's findings with aggregate data from similar sites when it is available, or to use your results to compare against future results of your organization.**

At any time after submitting your information, you can enter your username/password to view and/or print your self assessment report. However, you will not be able to make any changes to the information you originally submitted.

### Explanation of Scores

The assessment items have been scored as follows:

- A. Score = 0**  
There has been no activity to implement this item.
- B. Score = 1**  
This item has been formally discussed and considered, but it has not been implemented.
- C. Score = 2**  
This item has been partially implemented in the organization for some or all areas, patients, drugs, and/or staff.
- D. Score = 3**  
This item is fully implemented in the organization for some or all areas, patients, drugs, and/or staff.
- E. Score = 4**  
This item is fully implemented throughout the organization for all patients, drugs, and/or staff.
- N/A. Score = 1**  
(Not applicable)

## Instructions for Entering and Submitting Information to ISMP/ISMP Canada (continued)

### Access to Comparative Reports

Shortly following the final submission date of the **2012 ISMP International Medication Safety Self Assessment® for Oncology**, ISMP and ISMP Canada will prepare and make available to those organizations that participated, a **Preliminary Aggregate Results** workbook with comparative reports of the level of medication safety practices based on the data submitted. **Access to these aggregate comparative reports will be available using the same password you used when entering and submitting your information.** In addition, further analysis of the data will be completed, and the results will be submitted for publication in a peer-reviewed journal.

### Security and Protection of Self Assessment Information Submitted to ISMP/ISMP Canada

All information submitted to ISMP and ISMP Canada is maintained in a secure database maintained solely by ISMP Canada. The application does not allow viewing of data or demographic information associated with individual assessment information. All information is contextually de-identified, and the demographics and submitted results will be used only for aggregate data reports. Usernames/passwords required for submitting information to ISMP are self-selected by the organization/practice setting participating in the self assessment. Access to any contact information voluntarily provided by the organization (i.e., email address for lost or misplaced password only) is restricted to a small number of ISMP Canada personnel and confidentiality is assured.

In addition to the usual high standard of confidentiality associated with any information submitted to ISMP and ISMP Canada, we would also like to remind participants that ISMP is a federally certified patient safety organization (PSO) in the United States. If self assessment information is collected within the hospital's **patient safety evaluation system** and submitted to ISMP as **patient safety work product**, the information is granted protection from discovery in connection with a federal, state, or local civil, administrative, or disciplinary proceeding. No contract with ISMP is required for this legal protection. Further guidelines regarding submitting information to ISMP as a PSO can be found at:

[www.ismp.org/docs/PSOguidelines.pdf](http://www.ismp.org/docs/PSOguidelines.pdf).

## Demographics

**FAQ** - Please see the FAQs for information about completing the demographic information.

### 1a. Country

\_\_\_\_\_

### 1b. Province/State/Region/Territory

\_\_\_\_\_

### 2. Please check the one category that best describes the location of your organization/practice setting.

- Urban  
(a population of approximately 50,000 or more)
- Rural  
(a population less than 50,000)

### 3. Describe your organization/practice setting(s).

(If you have multiple practice settings, please complete a separate assessment for each setting that follows *different* procedures/processes for oncology medications.) **FAQ**

- Inpatient

#### 3a. Total beds

- Less than 100
- 100 to 299
- 300 to 499
- 500 and over

#### 3b. Percent oncology

- Less than 25%
- 25% to 49%
- 50% to 74%
- 75% to 100%

- Outpatient

#### 3c. Total chairs/beds

- Less than 10
- 10 to 19
- 20 to 49
- 50 and over

#### 3d. Percent oncology

- Less than 25%
- 25% to 49%
- 50% to 74%
- 75% to 100%

### 4. Please estimate your organization's/practice setting's oncology patient population.

- \_\_\_\_ % - Age 18 or less
- \_\_\_\_ % - Age 19 - 64
- \_\_\_\_ % - Age 65 and over

### 5. Are you an academic or university organization/practice setting (e.g., do you have a medical school affiliation)?

- Yes
- No

### 6. What is the form of ownership or funding for the organization/practice setting?

(select all that apply)

- Public (government or military)
- Private for-profit
- Private not-for-profit/charitable

### 7. Is your organization/practice setting part of a larger healthcare system with common ownership and/or governance?

- Yes
- No

### 8. Is your organization/practice setting a nationally/provincially/state designated cancer center in your country?

- Yes

#### 8a. If multiple sites, how many are designated?

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- More than 10
- No

## Demographics (continued)

- 9. What is the average number of chemotherapy/biotherapy doses administered per month at your organization/practice setting? [FAQ](#)**
- Less than 249
  - 250 - 999
  - 1000 - 2999
  - 3000 and over
- 10. Which of the following cancer treatments does your organization/practice setting provide?**  
(select all that apply)
- Alternative cancer therapies (e.g., homeopathic, naturopathic, acupuncture)
  - Blood and marrow transplants
  - Cancer vaccines
  - Chemoembolization (venous occlusion therapy)
  - Heated chemotherapy/biotherapy (hyperthermia)
  - High dose chemotherapy/biotherapy
  - Home care chemotherapy/biotherapy
  - Intramuscular chemotherapy/biotherapy
  - Intraoperative chemotherapy/biotherapy (e.g., isolated limb perfusions)
  - Intraperitoneal chemotherapy/biotherapy
  - Intrathecal chemotherapy/biotherapy (e.g., lumbar puncture, Ommaya reservoir)
  - Intravenous chemotherapy/biotherapy
  - Investigational chemotherapy/biotherapy
  - Oral chemotherapy/biotherapy
  - Radiolabeled chemotherapy/biotherapy
  - Special procedures (e.g., cystoscopic procedures, intraocular)
  - Subcutaneous chemotherapy/biotherapy
  - Other \_\_\_\_\_
- 11. Does your organization/practice setting participate in oncology-based research?**
- Yes
  - No
- 12. Does your organization/practice setting undergo specialty certification/accreditation for oncology from an external review agency (e.g., World Health Organization [WHO], National Cancer Institute [NCI], Det Norske Veritas [DNV])?**
- Yes
  - No
- 13. Has your organization/practice setting adopted chemotherapy/biotherapy safety standards or guidelines from recognized professional organizations (e.g., World Health Organization [WHO], International Society of Oncology Pharmacy Practitioners [ISOPP], American Society of Clinical Oncology/Oncology Nursing Society [ASCO/ONS], Clinical Oncological Society of Australia [COSA], Accreditation Canada, Canadian Association of Nurses in Oncology [CANO-ACIO], other national professional/accrediting organizations)?**
- Yes
  - No
- 14. What percentage of your professional staff is oncology trained/certified through an external accreditation/certification organization?**
- a. Pharmacists**
- None
  - 1% - 25%
  - 26% - 50%
  - 51% - 75%
  - 76% +
- b. Pharmacy Technicians**
- None
  - 1% - 25%
  - 26% - 50%
  - 51% - 75%
  - 76% +

[Question continued on next page]

## Demographics (continued)

**c. Physicians**

- None
- 1% - 25%
- 26% - 50%
- 51% - 75%
- 76% +

**d. Registered Nurses**

- None
- 1% - 25%
- 26% - 50%
- 51% - 75%
- 76% +

**e. Other** \_\_\_\_\_

- None
- 1% - 25%
- 26% - 50%
- 51% - 75%
- 76% +

**15. Does your organization/practice setting provide mandatory internal staff training/certification in oncology prior to providing oncology patient care?**

- Yes

**15a. For which HEALTHCARE PRACTITIONERS?**

(select all that apply)

- Pharmacists
- Pharmacy Technicians
- Physicians
- Registered Nurses
- Other \_\_\_\_\_

- No

**16. Who *prepares* chemotherapy/biotherapy for your organization/practice setting?**

(select all that apply)

- Pharmacists
- Pharmacy Technicians
- Physicians
- Registered Nurses
- Outsourced commercial compounding pharmacy
- Other \_\_\_\_\_

**17. Who is authorized to *check* the final chemotherapy/biotherapy product before it leaves the preparation area?**

(select all that apply)

- Pharmacists
- Pharmacy Technicians
- Physicians
- Registered Nurses
- Other \_\_\_\_\_

**18. Do you have computerized prescriber order entry (CPOE)?**

- Yes
- No

**19. How many standardized chemotherapy/biotherapy **ORDER SETS** (electronic and/or pre-printed) does your organization/practice setting have available to guide prescribing?**

- None
- 1 to 49
- 50 to 249
- 250 to 499
- 500 or more

**20. Spectrophotometry or similar chemical analysis technology is used for end-product testing to verify the contents (active ingredients and/or concentration) of chemotherapy/biotherapy compounding/admixture prior to dispensing.**

- Yes
- No



## Demographics (continued)

**21. Do you belong to a group purchasing/group service organization (GPO/GSO)?**

Yes

**21a. Select country**

Canada

**21a i. Which Organizations?**

(select all that apply)

Alberta Purchasing Connection (APC)

Approvisionnement Montreal

HealthPRO

Medbuy

Saskatchewan Association of Health Organizations (SAHO)

Other \_\_\_\_\_

USA

**21a ii. Which Organizations?**

(select all that apply)

Amerinet

Broadlane

Consorta

Department of Defense

HCA (Hospital Corporation of America)

MedAssets

ION (International Oncology Network)

Onmark, McKesson Specialty Care Solutions

Premier

US Oncology

Veteran's Affairs

Provista/Novation

UHC/Novation (University Health System Consortium)

VHA/Novation

Other \_\_\_\_\_

Other \_\_\_\_\_

No

**22. Has your organization completed an ISMP Medication Safety Self Assessment® for Hospitals?**

Yes

**22a. What year(s) did you complete the assessment?**

(select all that apply)

2012

2011

2010

2009

2008

2007

2006

2005

2004

2003

2002

2001

2000

No

**23. If you have received a code from ISMP or ISMP Canada to segregate your information as part of a collaborative, please insert it below. If you do not have a code, please leave blank. (optional) [FAQ](#)**

\_\_\_\_\_

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## I. PATIENT INFORMATION

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #1

Essential patient information is obtained, readily available in useful form, and considered when prescribing, dosing, scheduling, dispensing, administering, and monitoring chemotherapy, biotherapy, and treatment-related drugs.

<b>1</b>	A <b>STRUCTURED PROCESS</b> is in place to collect and verify the patient's first and last name, age or date of birth, and medical record number or other unique identifier.					
<b>2</b>	A <b>STRUCTURED PROCESS</b> is in place to collect and document in a designated location the <u>cancer diagnosis including stage and therapeutic goal</u> (e.g., curative, palliative), <u>comorbid and/or chronic conditions</u> (e.g., hypertension, diabetes, renal or liver impairment, pregnancy, lactation), and <u>performance status</u> (general well-being) based on standardized scale (e.g., Karnofsky scale or Eastern Cooperative Oncology Group [ECOG] <a href="http://en.wikipedia.org/wiki/Performance_status#Karnofsky_scoring">http://en.wikipedia.org/wiki/Performance_status#Karnofsky_scoring</a> ).					
<b>3</b>	Chemotherapy/biotherapy orders <u>cannot</u> be processed until the patient's <u>allergies</u> (e.g., drug, food, contrast media) and <u>associated reactions</u> have been identified, documented, and reviewed.					
<b>4</b>	Chemotherapy/biotherapy orders <u>cannot</u> be processed until the patient's <u>adverse drug reaction</u> history has been identified, documented, and reviewed.					
<b>5</b>	A <b>STRUCTURED PROCESS</b> is in place to collect and document in a designated location the patient's current immunization status.					
<b>6</b>	At the first <b>ENCOUNTER</b> of each treatment <b>CYCLE</b> , a <b>STRUCTURED PROCESS</b> is in place to obtain a list of current medications (including over-the-counter drugs, vitamins, herbals, recreational drugs, and homeopathic drugs) that the patient has been taking prior to the <b>ENCOUNTER</b> and this list is compared with the medications prescribed for the current <b>ENCOUNTER</b> and at any further <b>TRANSITION OF CARE</b> .					
<b>7</b>	A <b>STRUCTURED PROCESS</b> is in place to collect and document in a designated location the patient's current (actual) height and weight in metric units.					

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## I. PATIENT INFORMATION (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>8</b> <b>FAQ</b>	Placement and patency of access devices (e.g., peripheral IV access, infusion port, peripherally inserted central catheter [PICC] line) for intravenous chemotherapy administration is verified and documented <u>prior to preparation</u> of chemotherapy.					
<b>9</b>	A <b>STRUCTURED PROCESS</b> is in place to collect and document in a designated location the required informed consent for chemotherapy/biotherapy, prior to the initiation of treatment and when treatment changes.					
<b>10</b>	A <b>STRUCTURED PROCESS</b> is in place to collect and document in a designated location the patient's advanced directives, which may include resuscitation code status prior to the initiation of treatment and with patient status changes.					

### Core Characteristic #2

Essential patient information is used to monitor and manage the effects of chemotherapy, biotherapy, and treatment-related drugs and to adjust the treatment plan when indicated by evidence-based practices.

<b>11</b> <b>FAQ</b>	Authorized <b>HEALTHCARE PRACTITIONERS</b> can easily <u>and</u> electronically access laboratory values (inpatient and/or outpatient) while working in their respective locations.					
<b>12</b>	The <b>COMPUTER SYSTEM</b> used for medication order entry is <u>directly</u> interfaced with the laboratory system to <i>automatically</i> alert <b>HEALTHCARE PRACTITIONERS</b> to the need for potential drug therapy changes.					
<b>13</b>	General and treatment (drug) specific <u>baseline</u> diagnostic and laboratory test results are obtained and evaluated prior to administering the first dose of chemotherapy/biotherapy (e.g., Multi Gated Acquisition [MUGA] scan for anthracyclines, renal function tests for <b>CIS</b> platin-based toxicity).					
<b>14</b>	Current laboratory values are evaluated before and during each treatment <b>CYCLE</b> .					
<b>15</b>	Rules/guidelines/policies within your organization/practice setting define the timeframe for an acceptable "current" laboratory and/or diagnostic test (e.g., absolute neutrophil count 72 hours prior to treatment).					

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## I. PATIENT INFORMATION (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>16</b>	A defined process is in place to <i>obtain and communicate</i> to all authorized <b>LICENSED HEALTHCARE PRACTITIONERS</b> involved with the patient results of particular laboratory tests for specific drugs requiring specialized monitoring for known toxicities (e.g., <b>CIS</b> platin-induced renal toxicity).					
<b>17</b>	An authorized <b>LICENSED HEALTHCARE PRACTITIONER</b> <i>verifies</i> , using a standardized toxicity grading scale (internally or externally developed), the severity and nature of any previous adverse drug reactions related to the chemotherapy treatment (e.g., <b>riTUX</b> imab infusion rate-related reaction) <u>and</u> documents actions taken to prevent reoccurrence.					
<b>18</b>	Dose modification guidelines have been established for specific chemotherapy/biotherapy drugs <u>and</u> are considered based on the patient's laboratory results, toxicities, therapy reactions, and/or response.					
<b>19</b>	A system is in place (electronic or manual) to document, track, and communicate the lifetime cumulative dose of chemotherapy as appropriate (e.g., anthracyclines, bleomycin).					

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## II. DRUG INFORMATION

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #3

Essential drug information is readily available in useful form and considered when prescribing, dosing, scheduling, dispensing, administering, and monitoring chemotherapy, biotherapy, and treatment-related drugs.

<b>20</b>	All patient-care areas, where chemotherapy, biotherapy, and treatment-related drugs are prescribed, dispensed, and administered, are supplied with standardized oncology/drug references (text and/or electronic) <u>and</u> there is a process in place to update annually or as new versions become available.					
<b>21</b>	All <i>internally</i> developed chemotherapy, biotherapy, and treatment-related drug information tools (e.g., pocket references, drug information cards, standard preprinted <b>ORDER SETS</b> , <b>PROTOCOLS</b> or checklists, patient drug education material, compounding formulas) undergo a formal approval process (e.g., through an <b>AUTHORITATIVE COMMITTEE</b> ) <i>before</i> use, which includes an interdisciplinary review by primary users, and are dated and reviewed regularly.					
<b>22</b>	Current <b>PROTOCOLS</b> (both investigational and standard), guidelines, dosing formulas, <b>MAXIMUM DOSE</b> recommendations, and checklists for chemotherapy, biotherapy, and treatment-related drugs are standardized and readily accessible to all members of the <b>HEALTHCARE TEAM</b> .					
<b>23a</b> FAQ	All <i>inpatient</i> chemotherapy/biotherapy orders are entered into a computer and screened electronically against the patient's current medication and/or medical profile for contraindications, interactions, and appropriateness of doses <u>before</u> medications are administered.					<b>NOT APPLICABLE</b>
<b>23b</b> FAQ	All <i>outpatient</i> chemotherapy/biotherapy orders are entered into a computer and screened electronically against the patient's current medication and/or medical profile for contraindications, interactions, and appropriateness of doses <u>before</u> medications are administered.					<b>NOT APPLICABLE</b>
<b>24</b>	The <b>COMPUTER SYSTEM</b> performs dose-range checks, and warns <b>PRESCRIBERS</b> , pharmacists, and nurses about <i>overdoses</i> for all chemotherapy, biotherapy, and treatment-related drugs.					

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## II. DRUG INFORMATION (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>25</b>	A process is in place for a designated person to routinely test the <b>COMPUTER SYSTEM</b> to ensure that <b>MAXIMUM DOSE</b> alerts are present for chemotherapy, biotherapy, and treatment-related drugs <u>and</u> build <b>HARD STOPS</b> that cannot be overridden, as appropriate.					
<b>26</b>	The <b>COMPUTER SYSTEM</b> performs dose-range checks, and warns <b>PRESCRIBERS</b> , pharmacists, and nurses about <i>underdoses</i> for all chemotherapy, biotherapy, and treatment-related drugs.					
<b>27</b>	The <b>COMPUTER SYSTEM</b> dose-range checking feature can be modified to recognize <b>PROTOCOL</b> -specific dosing ranges.					
<b>28</b>	The <b>COMPUTER SYSTEM</b> has been programmed to exclude inappropriate routes of administration from selection choices, or it alerts the <b>HEALTHCARE PRACTITIONER</b> if an inappropriate route has been selected and prevents ( <b>HARD STOP</b> ) the order from being processed (e.g., vin <b>CRIST</b> ine cannot be ordered as an intrathecal injection).					
<b>29</b>	The process for adding a new drug to the <b>COMPUTER SYSTEM</b> includes testing to verify that important clinical warnings (e.g., serious drug interactions, allergies, <b>MAXIMUM DOSE</b> limits) are functional; <u>and</u> if a serious alert is not yet functional through the drug information system vendor, a temporary user-programmed alert is added so that it appears on the screen during order entry.					
<b>30</b>	<b>COMPUTER SYSTEM</b> drug information updates are obtained from a database vendor <u>and</u> loaded at least quarterly.					

### Core Characteristic #4

A controlled drug formulary incorporates specific requirements, restrictions, and considerations for chemotherapy, biotherapy, and treatment-related drugs and is driven by evidence-based treatment algorithms, strength of evidence compendia, and **PROTOCOLS**.

<b>31</b>	New chemotherapy/biotherapy drugs are considered through a formal process (e.g., <b>AUTHORITATIVE COMMITTEE</b> ), for use in the organization/practice setting (e.g., addition to the formulary) after review of all therapeutic equivalents, and their place in therapy (e.g., first line, second line) is evaluated based on strength of evidence.					
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## II. DRUG INFORMATION (continued)

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>32</b>	The ability of the organization/practice setting to adequately monitor and manage the anticipated adverse effects of a medication is investigated, documented, and addressed through a formal process (e.g., <b>AUTHORITATIVE COMMITTEE</b> ), <i>before</i> use in the organization/practice setting (e.g., addition to the formulary).					
<b>33</b>	When chemotherapy/biotherapy drugs are reviewed for use in the organization/practice setting (e.g., addition to the formulary), safety enhancements are established <i>before</i> initial use (e.g., standard <b>ORDER SETS</b> , prescribing guidelines).					
<b>34</b>	A <b>STRUCTURED PROCESS</b> is in place to identify emerging internal and external information (e.g., adverse reactions, changing indications, medication-related events) and re-evaluate the status of the drug on the formulary, including safety enhancements that may be required.					
<b>35</b>	Chemotherapy/biotherapy drugs not approved by the organization/practice setting (i.e., non-formulary) are used only when therapeutically necessary and appropriate and are reviewed through a formal process (e.g., <b>AUTHORITATIVE COMMITTEE</b> ).					
<b>36</b>	A process is in place to provide adequate information to <b>HEALTHCARE PRACTITIONERS</b> about all chemotherapy, biotherapy, and treatment-related drugs (approved, not approved, <b>SPECIAL ACCESS DRUGS</b> , or investigational drugs) before they are used by the organization/practice setting.					
<b>37</b> <b>FAQ</b>	An <b>AUTHORITATIVE COMMITTEE</b> (e.g., <b>INSTITUTIONAL REVIEW BOARD [IRB]</b> ) oversees the approval and use of investigational drugs and associated <b>PROTOCOLS</b> .					
		<b>NOT APPLICABLE</b>				

### III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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#### Core Characteristic #5

Methods of communicating chemotherapy/biotherapy orders, treatment-related medication orders, and other drug information are standardized and automated to minimize the risk for error. Chemotherapy/biotherapy orders contain **REDUNDANT** steps/checks to prevent errors.

<b>38</b>	Basic information (e.g., patient name, hospital unit location, birth date, physician) is clear and easily visible on orders transmitted to the pharmacy via addressograph imprints, labels on hard copy or facsimile, or sent electronically.					
<b>39</b>	<b>PRESCRIBERS</b> order chemotherapy, biotherapy, and treatment-related drugs during the patient <b>ENCOUNTER</b> or immediately after each <b>ENCOUNTER</b> , not at the conclusion of rounds or clinic hours.					
<b>40a</b> <b>FAQ</b>	<b>PRESCRIBERS</b> enter <i>inpatient</i> chemotherapy, biotherapy, and treatment-related medication orders into a <b>COMPUTER SYSTEM</b> that is <i>directly interfaced</i> with other <b>COMPUTER SYSTEMS</b> including pharmacy and nursing.					<b>NOT APPLICABLE</b>
<b>40b</b> <b>FAQ</b>	<b>PRESCRIBERS</b> enter <i>outpatient</i> chemotherapy, biotherapy, and treatment-related medication orders into a <b>COMPUTER SYSTEM</b> that is <i>directly interfaced</i> with other <b>COMPUTER SYSTEMS</b> including pharmacy and nursing.					<b>NOT APPLICABLE</b>
<b>41</b>	There is a defined process for immediately communicating order changes/clarifications and other interventions to the <b>HEALTHCARE TEAM</b> involved with the patient's care, including updating orders previously entered/processed.					
<b>42</b>	Standard <b>ORDER SETS</b> are used to guide prescribing for at least 75% of chemotherapy/biotherapy <b>PROTOCOLS</b> .					
<b>43</b>	Critical information (e.g., drug, dose, route, infusion rate, total volume, and duration) required for medication administration is displayed in the <i>same sequence using consistent terminology</i> in the medication orders, medication administration record (MAR), and on medication labels.					



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<b>E</b>	Fully implemented throughout

### III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION (continued)

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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#### Core Characteristic #6

Your organization/practice setting meets established standards for best practices designed to prevent errors related to chemotherapy, biotherapy, and treatment-related drug ordering.

<b>44</b>	Verbal/telephone orders are <u>never</u> accepted for chemotherapy/biotherapy <u>except</u> to hold or discontinue chemotherapy/biotherapy. (Faxed and emailed orders from the <b>PRESCRIBER</b> are considered written orders and are acceptable.)					
<b>45</b> FAQ	The <u>initial</u> <b>cycle</b> of chemotherapy/biotherapy to treat an oncologic diagnosis is ordered in detail by a <b>PRESCRIBER</b> with formal training in oncology (examples: board certification, therapy specific certification).					
<b>46</b> FAQ	<u>Subsequent</u> <b>cycles</b> of chemotherapy/biotherapy to treat an oncologic diagnosis are ordered in detail by a <b>PRESCRIBER</b> with formal training in oncology (examples: board certification, therapy specific certification).					
<b>47</b> FAQ	Chemotherapy/biotherapy order <u>changes/modifications</u> are ordered in detail by a <b>PRESCRIBER</b> with formal training in oncology (examples: board certification, therapy specific certification).					
<b>48</b>	Orders to “ <i>resume/continue chemotherapy/biotherapy</i> ” are <u>not</u> accepted.					
<b>49</b>	Guidelines are established for evaluating the patient at predetermined intervals between <b>cycles</b> of chemotherapy/biotherapy.					
<b>50</b>	All medications are ordered using the <u>generic</u> name of the medication (with the brand/trade name used for differentiation if required).					
<b>51</b>	Look-alike drug names are clearly distinguished in a way that differentiates them (e.g., use of <b>TALL MAN LETTERING</b> , use of brand name in parentheses) anywhere drug names are listed (e.g., order forms, computer screens, including automated dispensing cabinets, smart pumps).					

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<b>E</b>	Fully implemented throughout

### III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>52</b>	If an <b>ACRONYM</b> is used to identify the chemotherapy <b>PROTOCOL</b> , the <b>ACRONYM</b> is defined and each medication is prescribed individually, with the dose and schedule designated for each. (For example: CMV for bladder cancer is defined as <b>CIS</b> platin 100 mg/m <sup>2</sup> /day on Day 2, methotrexate 30 mg/m <sup>2</sup> /day on Day 1 and Day 8, vin <b>BLAS</b> tine 4 mg/m <sup>2</sup> /day on Day 1 and Day 8.)					
<b>53</b>	Chemotherapy/biotherapy infusion rates are expressed as mL/hour <u>and never</u> as mL/24 hours.					
<b>54</b>	Chemotherapy/biotherapy drugs for specific days are written explicitly (e.g., for parenteral administration, write as “Day 1, 2, 3”, and never as “Days 1-3”; for oral administration, write as “daily for 21 consecutive days and stop for 7 consecutive days”, and never as “Days 1-21, stop for Days 22-28”).					
<b>55</b>	<b>ORDER SETS</b> include the sequencing and timing of chemotherapy, biotherapy, and treatment-related drugs and all concurrent treatment-related modalities as appropriate (e.g., pre-medications, hydration, other supportive care medications, radiotherapy sequencing).					
<b>56</b>	The current <b>CYCLE</b> and the day within the <b>CYCLE</b> of chemotherapy (e.g., <b>CYCLE</b> 3 of 6, day 3 of 5) is verified against an established treatment <b>PROTOCOL</b> and is documented before each dose is administered.					
<b>57</b>	A mechanism is in place to ensure the correct interval/rest period between <b>CYCLES</b> has elapsed prior to initiating the next <b>CYCLE</b> of chemotherapy/biotherapy.					
<b>58</b>	A <b>STRUCTURED PROCESS</b> is in place to follow-up with patients who miss their scheduled appointments.					
<b>59</b>	A literature/compendia reference and patient-specific monitoring plan are provided at the time of ordering for all chemotherapy/biotherapy that is prescribed outside of generally established guidelines.					
<b>60</b> <b>FAQ</b>	A list of prohibited <i>error-prone abbreviations</i> (e.g., u, qd, MSO <sub>4</sub> , MTX, 6-MP, 5FU) is established for written and electronic communication of all drug orders.					

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<b>E</b>	Fully implemented throughout

### III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION (continued)

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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#### Core Characteristic #7

Your organization/practice setting meets established standards for best practices designed to prevent errors related to chemotherapy, biotherapy, and treatment-related drug dosing.

<b>61</b>	The <b>PRESCRIBER</b> documents on the order which “dosing weight,” (i.e., <b>ACTUAL WEIGHT, IDEAL WEIGHT, or ADJUSTED WEIGHT</b> ) will be used to calculate the dose of the chemotherapy/biotherapy.					
<b>62</b>	<b>IDEAL WEIGHT</b> or <b>ADJUSTED WEIGHT</b> (in metric units) is calculated using a standard method defined by your organization/practice setting.					
<b>63</b>	The patient’s <b>BODY SURFACE AREA (BSA)</b> is calculated before each <b>CYCLE</b> of chemotherapy/biotherapy, using a standard method defined by your organization/practice setting.					
<b>64</b>	Creatinine clearance is calculated before each <b>CYCLE</b> of chemotherapy/biotherapy, using a standard method defined by your organization/practice setting.					
<b>65</b>	For chemotherapy/biotherapy requiring the use of <b>AREA UNDER THE CURVE (AUC)</b> for dose calculation, the <b>AUC</b> is calculated before each <b>CYCLE</b> of chemotherapy/biotherapy, using a standard method defined by your organization/practice setting.					
<b>66</b>	<b>PRESCRIBERS</b> include the patient-specific dose and the mg/kg, mg/m <sup>2</sup> , units/m <sup>2</sup> , or other dosing method used to calculate the patient-specific dose for all chemotherapy and biotherapy drug orders (e.g., for a 1.67 m <sup>2</sup> patient: 240 mg/m <sup>2</sup> ; dose = 400 mg).					
<b>67</b>	Oral and parenteral doses of chemotherapy, biotherapy, and treatment-related drugs are expressed by metric weight or activity units only (e.g., mg, units) <u>not</u> by volume (e.g., mL, teaspoon) or number of dosage forms (e.g., tablets or vials).					
<b>68</b>	Trailing zeros are <u>never</u> used after a decimal in a dose expression (e.g., use 10 mg <u>not</u> 10.0 mg).					
<b>69</b>	Leading zeros are <u>always</u> used before a decimal for doses less than 1 (e.g., 0.1 mg <u>not</u> .1 mg).					

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<b>B</b>	Formally considered, but not implemented
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<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

### III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>70</b>	Writing the total chemotherapy/biotherapy dose for the entire <b>cycle</b> of treatment is prohibited (e.g., order should be written as 400 mg/m <sup>2</sup> on day 1, 2, 3, and 4, <u>not</u> as 1,600 mg/m <sup>2</sup> over 4 days).					
<b>71</b>	The infusion rate or duration of infusion (including titration parameters) is defined in the order (e.g., infuse at 100 mL/hour; infuse over 4 hours).					
<b>72</b>	A standardized rounding procedure is established and followed throughout the organization/practice setting for parenteral doses, unless otherwise required by an investigational <b>PROTOCOL</b> (e.g., calculated chemotherapy/biotherapy doses less than 10 mg are rounded to the nearest tenth [e.g., 7.76 mg is rounded to 7.8 mg] and doses greater than or equal to 10 mg are rounded to the closest whole number [e.g., 31.2 mg is rounded to 31 mg]).					
<b>73</b>	The processes used to ensure the safety of orders for <u>oral</u> and other non-parenteral dosage forms of chemotherapy/biotherapy are the same as those in place for parenteral dosage forms.					
<b>74</b>	Steps are taken to round doses of <u>oral</u> chemotherapy/biotherapy drugs to match commercially available strengths/concentrations when calculating dose requirements, whenever possible.					
<b>75</b> <b>FAQ</b>	For intermittent treatment with oral chemotherapy/biotherapy drugs, the quantity of drugs prescribed and dispensed for ambulatory patients (e.g., number of tablets/capsules) is the exact quantity required by the patient for a specified timeframe (e.g., capecitabine is available in 500 mg tablets; one <b>cycle</b> of treatment is ordered for capecitabine 1,250 mg/m <sup>2</sup> [ <b>BSA</b> = 1.6 m <sup>2</sup> ] twice a day for 2 weeks = 2,000 mg twice a day for 2 weeks = 112 tablets).					
<b>NOT APPLICABLE</b>						

#### Core Characteristic #8

Your organization/practice setting follows the safety strategies recommended by the World Health Organization (WHO) for vin**CRIS**tine (and other vinca alkaloids as applicable).

<b>76</b>	Vin <b>CRIS</b> tine is dispensed in a minibag of a compatible solution (e.g., 25 mL for pediatric patients and 50 mL for adults). Vin <b>CRIS</b> tine doses are <u>never</u> dispensed and/or administered using a syringe.					
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### III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION (continued)

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	
<b>77</b> FAQ	VinCRISTine is dispensed with a prominent warning label that reads: FOR INTRAVENOUS USE ONLY - FATAL IF GIVEN BY OTHER ROUTES.						
<b>78</b> FAQ	The presence of vinCRISTine is prohibited in areas where intrathecal medications are administered and/or stored.	<b>NOT APPLICABLE</b>					
<b>79</b> FAQ	Confirmation that the administration of any prescribed intrathecal medications has been completed is required before dispensing vinCRISTine.	<b>NOT APPLICABLE</b>					

## IV. DRUG LABELING, PACKAGING, AND NOMENCLATURE

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #9

Well-designed, readable labels that clearly identify medications as chemotherapy/biotherapy are present on all medication containers, and medications remain labeled up to the completion of drug administration.

<b>80</b>	All drug labels are typed or computer generated <u>and</u> not handwritten.					
<b>81</b>	All chemotherapy/biotherapy drugs ( <u>oral and parenteral</u> ) are dispensed with auxiliary labels, on the primary container and the transport container, (e.g., "Chemotherapy") so that it is easily identified and understood as being cytotoxic.					
<b>82</b> FAQ	Auxiliary warning labels are applied to products intended for intrathecal administration (e.g., <i>For Intrathecal Use Only</i> ).	<b>NOT APPLICABLE</b>				
<b>83a</b> FAQ	Pharmacy-generated chemotherapy/biotherapy labels are <i>designed</i> , with input from the disciplines who use them, to ensure that critical information (including regulatory requirements) is displayed in a standardized format using consistent terminology and that non-essential information is avoided.					
<b>83b</b> FAQ	Pharmacy-generated chemotherapy/biotherapy labels are <i>reviewed periodically</i> , with input from the disciplines who use them, to ensure that critical information (including regulatory requirements) is displayed in a standardized format using consistent terminology and that non-essential information is avoided.					
<b>84</b>	There is a standard process to identify the overfill volume on the pharmacy label for compounded IV chemotherapy/biotherapy solutions.					
<b>85</b>	The concentration of parenteral chemotherapy/biotherapy is expressed on the label as the <u>total dose</u> in <u>total volume</u> of solution in the container (e.g., 2 mg in 10 mL).					
<b>86</b>	The <i>ISMP Medication Safety Alert!</i> <sup>®</sup> and/or other current literature is regularly reviewed to identify chemotherapy/biotherapy drug labeling, packaging, and nomenclature problems, <u>and</u> action is taken to prevent errors with these drugs.					

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## V. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #10

Strategies are established to minimize the possibility of errors in the chemotherapy/biotherapy acquisition, storage, production, and distribution process.

<b>87</b>	All chemotherapy, biotherapy, and treatment-related drugs that are administered to patients are prepared/mixed on site or provided directly to the facility by an accredited/certified chemotherapy compounding facility.					
<b>88</b>	Chemotherapy/biotherapy drugs are purchased from authorized distributors or manufacturers who can verify the source of the drug.					
<b>89</b>	Chemotherapy/biotherapy drugs that are purchased from authorized distributors or manufacturers are received from external sources in sealed, leak-proof shipping containers that are labeled as containing chemotherapy or hazardous material.					
<b>90</b>	Chemotherapy/biotherapy (both oral and parenteral) is safely stored in a separate designated area of the pharmacy with appropriate signage to warn of hazards <u>and</u> refrigerated chemotherapy/biotherapy medications are segregated from other medications.					
<b>91 FAQ</b>	Pharmacy oversees the storage, preparation, dispensing, and tracking of investigational drugs (chemotherapy, biotherapy, and treatment-related).					<b>NOT APPLICABLE</b>
<b>92 FAQ</b>	The use of radiolabeled chemotherapy/biotherapy drugs follows appropriate safety standards and is under the control of nuclear medicine.					<b>NOT APPLICABLE</b>
<b>93</b>	Strategies are in place for storing and dispensing chemotherapy, biotherapy, and treatment-related drugs with look-alike drug names and/or packaging that are known to be problematic and have caused medication errors (e.g., segregated storage, use of <b>TALL MAN LETTERING</b> [e.g., vin <b>CRIS</b> tine and vin <b>BLAS</b> tine], auxiliary warnings).					
<b>94</b>	All chemotherapy/biotherapy drugs are provided to patient care areas in a form that requires no further preparation by the <b>LICENSED HEALTHCARE PRACTITIONER</b> who will be administering the medication (e.g., the medication will be in a syringe or infusion bag ready for administration).					

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<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## V. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION (continued)

		A	B	C	D	E
<b>95</b> FAQ	Commercially available standard base solutions (e.g., sodium chloride 0.9%, dextrose 5% in water) are used for chemotherapy/biotherapy preparation and not compounded by the facility.					
<b>96</b> FAQ	If <i>non-standard</i> concentrations of base solutions that require specialty compounding are needed, their use is minimized and the clinical rationale is documented.	<b>NOT APPLICABLE</b>				
<b>97</b>	All chemotherapy/biotherapy is prepared for <i>one patient</i> at a time and chemotherapy/biotherapy products are prepared <i>individually</i> (only one drug/compound preparation is handled in the <b>BIOLOGIC SAFETY CABINET/ISOLATOR</b> at a time).					
<b>98</b>	When preparing chemotherapy/biotherapy drug <b>BATCHES</b> (the preparation of multiple units of the same drug with the same concentration in the same diluent and final volume – at one time – that can be used for multiple patients), only one drug and one concentration is prepared at a time.					
<b>99</b>	When parenteral chemotherapy/biotherapy products are prepared, a second authorized <b>LICENSED HEALTHCARE PRACTITIONER</b> verifies the correct drug, diluent, and corresponding volumes <u>prior</u> to addition to the final container/base solution. (The syringe <b>PULLBACK METHOD</b> of verification is <u>not</u> used.)					

### Core Characteristic #11

Chemotherapy, biotherapy, and treatment-related drugs are provided to patient care areas in a safe and secure manner and available for administration within a timeframe that meets essential patient needs.

<b>100</b>	The system used to physically deliver chemotherapy/biotherapy from the pharmacy to patient care areas is <i>controlled</i> by the pharmacy and includes transport in a sealed, leak-proof bag/container labeled as chemotherapy or hazardous material.					
<b>101</b>	Chemotherapy/biotherapy (both oral and parenteral) is <u>always</u> hand delivered (e.g., never sent through a pneumatic tube system).					
<b>102</b>	When chemotherapy/biotherapy is delivered to a patient care area, it is provided directly to a qualified chemotherapy nurse (preferably the nurse caring for the patient) or placed in a designated, segregated storage area.					



## V. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION (continued)

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>103</b>	Defined timeframes for ordering and preparing chemotherapy/biotherapy medications are established <u>and</u> followed.					
<b>104</b>	Guidelines and antidotes for treating chemotherapy/biotherapy <i>extravasations</i> are readily available in the area where chemotherapy is being administered.					
<b>105</b>	Guidelines and antidotes for treating chemotherapy/biotherapy <i>hypersensitivity reactions</i> are readily available in the area where chemotherapy is being administered.					
<b>106</b>	Guidelines for treating oncologic emergencies (e.g., tumor lysis syndrome, superior vena cava syndrome) have been established and are readily available.					

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## VI. MEDICATION DEVICE ACQUISITION, USE, AND MONITORING

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #12

The potential for human error is mitigated through careful standardization, procurement, use, and maintenance of devices used to prepare and administer chemotherapy, biotherapy, and treatment-related drugs.

<b>107</b>	The types of infusion devices used for chemotherapy/biotherapy administration are limited to maximize competence with their use within the organization/practice setting.					
<b>108</b>	Guidelines have been established to maintain, clean, and certify the equipment used to prepare and administer chemotherapy/biotherapy.					
<b>109</b>	Infusion pumps/controlled rate devices are used for the administration of all <b>INTERMITTENT INTRAVENOUS INFUSIONS</b> and <b>CONTINUOUS INTRAVENOUS INFUSIONS</b> containing chemotherapy/biotherapy.					
<b>110</b>	<b>INTRAVENOUS PUSH</b> chemotherapy/biotherapy drugs that are known vesicants are administered through a side arm port on the intravenous tubing while a compatible base solution is infusing. Syringe pumps are not used for <b>INTRAVENOUS PUSH</b> vesicants.					
<b>111</b> FAQ	Multichannel infusion pumps are used for only <i>one</i> patient at a time.	<b>NOT APPLICABLE</b>				
<b>112</b> FAQ	Where disposable controlled rate devices (e.g., elastomeric) are used for the administration of chemotherapy/biotherapy, there is a process in place to ensure that the appropriate device is selected.	<b>NOT APPLICABLE</b>				
<b>113</b>	Smart infusion pumps are used for the IV administration of chemotherapy/biotherapy, and <b>SOFT STOPS</b> and <b>CATASTROPHIC STOPS</b> are employed to intercept and prevent wrong dose/wrong infusion rate errors due to misprogramming the pump, miscalculation, or an inaccurately prescribed medication.					
<b>114</b>	The distal ends of all tubing are clearly labeled with the <i>route of administration</i> for patients who are receiving chemotherapy/biotherapy and other treatments via various routes (e.g., bladder, IV, central venous, arterial).					
<b>115</b>	The distal ends of all tubing on all chemotherapy/biotherapy infusions are clearly labeled as <i>containing</i> chemotherapy/biotherapy.					

## VI. MEDICATION DEVICE ACQUISITION, USE, AND MONITORING (continued)

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>116</b>	When multiple chemotherapy/biotherapy infusions are being administered intravenously, the distal ends of all tubing are clearly labeled with the <i>drug name</i> .					

## VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS

<b>A</b>	No activity to implement
<b>B</b>	Formally considered, but not implemented
<b>C</b>	Partially implemented in some or all areas
<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #13

Chemotherapy, biotherapy, and treatment-related drugs are prescribed, dosed, scheduled, prepared, dispensed, administered, and stored with appropriate oversight and equipment to address occupational health and safety needs of personnel and in a physical environment that offers adequate space and lighting and minimizes distractions.

<b>117</b>	All areas where chemotherapy/biotherapy is prepared are under the control of pharmacy or have pharmacy oversight (e.g., a consultant pharmacist).					
<b>118a</b> FAQ	Pharmacists with oncology training regularly (e.g., one 8-hour shift per 24 hours) practice in <i>inpatient</i> care areas where chemotherapy/biotherapy is ordered and administered performing clinical activities (i.e., reviewing patient records and medication orders, attending interdisciplinary rounds, providing input into the selection and administration of medications, educating patients, and monitoring the effects of medications on patients).					<b>NOT APPLICABLE</b>
<b>118b</b> FAQ	Pharmacists with oncology training regularly (e.g., one 8-hour shift per 24 hours) practice in <i>outpatient</i> care areas where chemotherapy/biotherapy is ordered and administered performing clinical activities (i.e., reviewing patient records and medication orders, attending interdisciplinary rounds, providing input into the selection and administration of medications, educating patients, and monitoring the effects of medications on patients).					<b>NOT APPLICABLE</b>
<b>119</b>	A <b>STRUCTURED PROCESS</b> is in place to <u>immediately</u> return discontinued/unused chemotherapy/biotherapy medications to the pharmacy or place them in a separate/secure area until pharmacy pick-up.					
<b>120</b>	Eyewash stations and safety showers are accessible in all areas where chemotherapy/biotherapy is stored, prepared, and administered.					
<b>121</b>	Lighting is adequate (illumination levels around 100 foot-candles) to clearly read labels and other important drug and patient information in pharmacies, patient unit medication rooms, patient rooms, and at automated dispensing cabinets (ADCs).					

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<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

## VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>122</b>	Pharmacies and patient unit medication rooms (or areas) have adequate space for storage of drugs, intravenous solutions, and drug supplies.					
<b>123</b>	Medication preparation areas in the pharmacy and on patient care units are isolated and relatively free of distractions, interruptions, and noise (not greater than 50 decibels [dBA]).					
<b>124</b>	Appropriate <b>PERSONAL PROTECTIVE EQUIPMENT (PPE)</b> is used when <i>administering</i> and/or <i>handling</i> chemotherapy.					
<b>125</b>	Guidelines and kits (including <b>PERSONAL PROTECTIVE EQUIPMENT [PPE]</b> ) for chemotherapy/biotherapy spills are readily available for immediate use.					
<b>126</b>	Chemotherapy/biotherapy drugs are prepared in a designated area with restricted access, segregated from the production area for other sterile products (e.g., in a negative pressure environment and using an appropriately ventilated <b>BIOLOGICAL SAFETY CABINET/ISOLATOR</b> ).					
<b>127</b>	A <b>BIOLOGICAL SAFETY CABINET/ISOLATOR</b> , certified by qualified personnel <i>annually</i> or as required by governing bodies, and <b>PERSONAL PROTECTIVE EQUIPMENT (PPE)</b> are used when preparing chemotherapy/biotherapy.					
<b>128a</b>	Oral chemotherapy/biotherapy that needs to be manipulated from its original form (e.g., crushed, split, opened, or dissolved) is first checked against a published reference (e.g., “Do Not Crush” List <a href="http://www.ismp.org/Tools/DoNotCrush.pdf">http://www.ismp.org/Tools/DoNotCrush.pdf</a> ).					
<b>128b</b>	If the chemotherapy/biotherapy drug is to be manipulated, this is <u>always</u> done in a controlled environment, such as a <b>BIOLOGICAL SAFETY CABINET/ISOLATOR</b> and using appropriate <b>PERSONAL PROTECTIVE EQUIPMENT (PPE)</b> .					
<b>129</b>	A <b>STRUCTURED PROCESS</b> is in place to avoid priming and/or flushing intravenous lines with chemotherapy/biotherapy containing fluids.					
<b>130 FAQ</b>	Guidelines are established for the safe and appropriate use of <b>CLOSED SYSTEM TRANSFER DEVICES</b> .					
<b>NOT APPLICABLE</b>						

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<b>E</b>	Fully implemented throughout

## VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>131</b>	When handling patient body fluids and excretions, appropriate <b>PERSONAL PROTECTIVE EQUIPMENT (PPE)</b> is used for a minimum of 48 hours post-administration of chemotherapy/biotherapy.					
<b>132</b>	A <b>STRUCTURED PROCESS</b> is in place to monitor the health effects of chemotherapy exposure on staff who are routinely involved in handling, preparing, distributing, administering, and disposing of chemotherapy/biotherapy.					
<b>133</b>	A <b>STRUCTURED PROCESS</b> is in place for environmental monitoring for chemotherapy/biotherapy contamination in all areas of preparation and administration.					
<b>134</b>	For staff involved in the handling of chemotherapy/biotherapy who are attempting to conceive, are pregnant or breastfeeding, a <b>STRUCTURED PROCESS</b> is in place to review potential exposure risks and offer alternative work assignment.					

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## VIII. STAFF COMPETENCY AND EDUCATION

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #14

All members of the **HEALTHCARE TEAM** involved in handling, prescribing, dispensing, administering, and disposing of chemotherapy/biotherapy, and monitoring patients receiving chemotherapy, biotherapy, and treatment-related drugs undergo a standardized orientation that includes baseline competency evaluation of knowledge and skills related to safe medication practices with chemotherapy/biotherapy and annual re-evaluation.

<b>135</b>	The organization/practice setting has a comprehensive orientation and baseline competency assessment program for <i>new staff</i> who handle, prescribe, prepare, administer, monitor, or dispose of chemotherapy/biotherapy.					
<b>136</b>	The organization/practice setting <i>annually</i> reassesses competency for all staff who handle, prescribe, prepare, administer, monitor, or dispose of chemotherapy/biotherapy.					
<b>137</b>	The organization/practice setting provides ongoing continuing education in oncology for the <b>HEALTHCARE TEAM</b> involved with the handling, prescribing, preparing, administering, monitoring, or disposing of chemotherapy/biotherapy.					
<b>138</b>	During orientation and on a routine basis, clinical and support staff receive information about the organization's actual medication errors (with emphasis on chemotherapy/biotherapy-related errors) as well as published medication errors that have occurred in other facilities, and they are educated about system-based strategies to reduce the risk of such errors.					
<b>139</b>	All staff involved with the use of devices for the <i>preparation</i> and <i>administration</i> of chemotherapy/biotherapy are educated about the use of the devices and are <i>tested for competency</i> prior to using these devices (e.g., <b>CLOSED SYSTEM TRANSFER DEVICES</b> , infusion pumps, disposable infusion devices [e.g., elastomeric]).					
<b>140</b>	Specialty access devices (e.g., hepatic arterial pump, Ommaya reservoir) can only be used by staff who have been trained and demonstrate <i>initial and ongoing competency</i> .					

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<b>E</b>	Fully implemented throughout

## VIII. STAFF COMPETENCY AND EDUCATION (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>141</b> <b>FAQ</b>	An oncology trained <b>HEALTHCARE PRACTITIONER</b> accompanies patients to other treatment/diagnostic departments (e.g., radiation, radiology) if they have chemotherapy/biotherapy drugs infusing parenterally and a defined handoff process occurs.					
		<b>NOT APPLICABLE</b>				
<b>142</b>	<b>LICENSED HEALTHCARE PRACTITIONERS</b> who prescribe, dispense, and administer chemotherapy/biotherapy are trained to anticipate, identify, and manage chemotherapy/biotherapy-induced toxicities.					
<b>143</b>	A <b>STRUCTURED PROCESS</b> is in place to ensure that staff competent in the preparation, administration, and monitoring of chemotherapy/biotherapy drugs are available <i>at all times</i> , including on days when staffing is short due to illness, vacation, educational absences, and fluctuations in patient acuity and workload.					



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<b>E</b>	Fully implemented throughout

## IX. PATIENT EDUCATION

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #15

Patients and/or family/caregivers/legal decision makers are included as active partners in their care, educated about their chemotherapy, biotherapy, and treatment-related drugs and are taught ways to prevent medication errors.

<b>144</b>	<b>PRESCRIBERS</b> and other <b>LICENSED HEALTHCARE PRACTITIONERS</b> educate patients and/or family/caregivers/legal decision makers, in their primary language and appropriate comprehension level, about recommended chemotherapy/biotherapy and therapy alternatives including the general treatment plan, side effects, etc., <i>prior to the selection</i> of the treatment <b>PROTOCOL</b> .					
<b>145</b>	Before the <i>first dose</i> of chemotherapy/biotherapy is administered, designated <b>LICENSED HEALTHCARE PRACTITIONERS</b> provide patients and/or family members/caregivers/legal decision makers with the treatment <b>PROTOCOL</b> (schedule), brand and generic name of the drug(s), the general purpose of the drug(s), the prescribed dose(s) and duration of therapy, immediate and delayed side effects, and when to seek medical help.					
<b>146</b>	Before the <i>first dose</i> of chemotherapy/biotherapy is administered, patients are educated about the potential reproductive risks (e.g., birth defects, infertility, pregnancy termination) associated with receiving chemotherapy/biotherapy.					
<b>147</b>	Ongoing education and dialogue about the treatment <b>PROTOCOL</b> is provided with each subsequent dose/ <b>CYCLE</b> of chemotherapy/biotherapy to ensure understanding and compliance.					
<b>148a</b>	Patients and/or caregivers receive both written and verbal instructions and educational material (in their primary language and comprehension level) to guide care in the home.					
<b>148b</b>	A <b>STRUCTURED PROCESS</b> is in place to measure patient's and/or caregiver's comprehension about information/instructions that were provided (e.g., teach-back method).					
<b>149</b>	Patients are educated about personal safety pertaining to the handling, storage, and disposal of their chemotherapy/biotherapy drugs and infusion devices.					

## IX. PATIENT EDUCATION (continued)

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<b>D</b>	Fully implemented in some areas
<b>E</b>	Fully implemented throughout

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>150</b>	<b>LICENSED HEALTHCARE PRACTITIONERS</b> educate patients about the potential for medication errors associated with chemotherapy/biotherapy drug administration (e.g., taking capecitabine daily for three weeks instead of taking it for two weeks then stopping it for one week, then repeating the <b>CYCLE</b> as ordered by the <b>PRESCRIBER</b> ).					

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<b>E</b>	Fully implemented throughout

## X. QUALITY PROCESSES AND RISK MANAGEMENT

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #16

A safety-supportive **JUST CULTURE** and model of shared accountability for safe **SYSTEM DESIGN** and making safe **BEHAVIORAL CHOICES** is in place and supported by management, senior administration, and the **BOARD OF TRUSTEES/DIRECTORS**.

<b>151</b>	Competency and performance evaluations are not based on the presence or absence of errors.					
<b>152</b>	Error prevention strategies focus on <b>SYSTEM DESIGN</b> enhancements that prevent harmful errors and management of safe <b>BEHAVIORAL CHOICES</b> of all staff.					
<b>153</b>	A <b>STRUCTURED PROCESS</b> is in place to ensure a rapid interdisciplinary response to a concern that something is occurring with the patient that could lead to serious harm, including contacting external sources for advice (e.g., a poison center, other drug information centers).					
<b>154</b>	The organization/practice setting has a clear and effective path for the <b>HEALTHCARE TEAM</b> to follow to resolve conflicts when <b>PRESCRIBERS</b> and/or supervisors do not agree with their expressed concerns about the safety of an order for chemotherapy/biotherapy.					
<b>155</b>	<b>PRESCRIBERS</b> and other members of the <b>HEALTHCARE TEAM</b> report and openly discuss errors including close calls without embarrassment or fear of reprisal from the organization/practice setting.					
<b>156</b>	All medication errors, as defined by the organization/practice setting, that reach the patient, regardless of the level of harm that results, are fully disclosed to patients/families in a timely manner.					
<b>157</b>	All members of the <b>HEALTHCARE TEAM</b> involved in errors that cause patient harm are emotionally supported by leadership and their colleagues <u>and</u> offered appropriate counseling by a qualified professional (e.g., through an employee assistance program.)					

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<b>E</b>	Fully implemented throughout

## X. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
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### Core Characteristic #17

Members of the **HEALTHCARE TEAM** are encouraged to detect and report chemotherapy/biotherapy errors, and interdisciplinary teams regularly analyze chemotherapy/biotherapy errors that have occurred within the organization/practice setting and in other organizations for the purpose of redesigning systems to best support safe **HEALTHCARE PRACTITIONER** performance.

<b>158</b> <b>FAQ</b>	The organization/practice setting has designated at least one trained <b>HEALTHCARE PRACTITIONER</b> to specifically enhance the detection of medication errors, oversee analysis of their causes, and coordinate an effective error-reduction plan.					
<b>159</b>	A <b>STRUCTURED PROCESS</b> is in place for a designated person to routinely review, for quality improvement purposes, reports of selected computer warnings (e.g., <b>MAXIMUM DOSE</b> alerts, serious drug interactions, allergy alerts) that are overridden.					
<b>160</b>	A clear definition (e.g., National Coordinating Council for Medication Error Reporting and Prevention [NCC MERP] <a href="http://www.nccmerp.org/aboutMedErrors.html">http://www.nccmerp.org/aboutMedErrors.html</a> ) of a medication error has been established and disseminated to all the members of the <b>HEALTHCARE TEAM</b> .					
<b>161</b>	All members of the <b>HEALTHCARE TEAM</b> are expected to report hazardous situations that <i>could lead</i> to an error, errors that have been detected and corrected <i>before they reach a patient</i> , and errors that have reached the patient (including omissions).					
<b>162</b>	Errors that are detected are reported, analyzed, and used by an established interdisciplinary oncology team for quality improvement activities for <b>SYSTEM REDESIGN</b> .					
<b>163</b>	All members of the <b>HEALTHCARE TEAM</b> who have been directly involved in a serious or potentially serious medication error participate in a <b>ROOT CAUSE ANALYSIS</b> of that error and assist with the development of <b>SYSTEM DESIGN</b> enhancements to reduce the potential for future errors.					
<b>164</b>	In addition to <b>HEALTHCARE PRACTITIONER</b> -reported incidents, other information is used to identify system-based problems (e.g., random chart review using <b>TRIGGERS</b> , observational methods of error detection, measuring compliance with new medication <b>PROTOCOLS</b> , drug use evaluations).					

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## X. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

		A	B	C	D	E
<b>165</b>	An established interdisciplinary oncology team reviews external information (published error reports or hazardous situations <i>from other organizations</i> ) to <u>proactively</u> target improvements in the medication use process for chemotherapy/biotherapy.					
<b>166</b>	An established interdisciplinary oncology team, that includes frontline staff, reviews the chemotherapy/biotherapy medication use process at least annually (e.g., using a <b>PROACTIVE RISK ASSESSMENT</b> tool such as this self assessment) to identify potential risk factors for medication errors.					

### Core Characteristic #18

Simple **REDUNDANCIES** that support a system of **INDEPENDENT DOUBLE CHECKS** or an automated verification process are used for vulnerable parts of the medication use process for chemotherapy/biotherapy to detect and correct serious errors before they reach patients.

<b>167 FAQ</b>	The procedure followed by nurses and pharmacists for double checking all prescribed chemotherapy/biotherapy doses includes verification of the <b>BSA</b> (m <sup>2</sup> ) using the patient's height and weight (in metric units) entered into the computer <u>and</u> recalculation of the actual dose (mg/m <sup>2</sup> or mg/kg).					
<b>168</b>	A pharmacist verifies that the dosing method used to calculate the patient-specific dose (e.g., mg/kg, mg/m <sup>2</sup> , units/m <sup>2</sup> , or <b>AREA UNDER THE CURVE</b> ) matches the <b>PROTOCOL</b> or treatment plan, and then conducts and documents (e.g., with initials or electronically) a double check of the <b>PRESCRIBER'S</b> calculated dose <i>before preparing and dispensing the drug</i> .					
<b>169</b>	Printed labels are matched with the original order (written or electronic) before chemotherapy/biotherapy is prepared.					
<b>170</b>	The base solution and all additives (including the drug, dose, volume drawn into each syringe, diluents, actual drug containers) for <i>chemotherapy/biotherapy admixtures</i> are <b>INDEPENDENTLY DOUBLE CHECKED</b> by a <b>LICENSED HEALTHCARE PRACTITIONER</b> and documented (e.g., with initials or electronically) before compounding the admixtures.					

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<b>E</b>	Fully implemented throughout

## X. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

		<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>171</b>	Nurses perform an <b>INDEPENDENT DOUBLE CHECK</b> of the <b>PRESCRIBER'S</b> calculated dose for chemotherapy/biotherapy according to the <b>PROTOCOL</b> or treatment plan <i>before administering</i> the drug and then document (e.g., with initials or electronically) in the patient's record.					
<b>172</b>	Immediately before administering the chemotherapy/biotherapy, a <b>TIME-OUT</b> is conducted by two <b>LICENSED HEALTHCARE PRACTITIONERS</b> to <b>INDEPENDENTLY DOUBLE CHECK</b> the correct patient, and comparing the drug label to the order/medication administration record, verify the drug, diluent, dose, route, rate, as well as pump setting, pump channel, and line attachment as applicable.					
<b>173</b>	With each new bag/bottle, or change in the rate of infusion, of chemotherapy/biotherapy, two <b>LICENSED HEALTHCARE PRACTITIONERS</b> independently (using a <b>TIME-OUT</b> ) confirm the correct patient, compare the drug label to the order/medication administration record, and verifying the drug, diluent, dose, route, rate, pump setting, pump channel, and line attachment immediately before starting/resuming the infusion.					
<b>174</b>	Machine-readable coding (e.g., bar coding) is used to verify drug selection prior to <i>dispensing</i> chemotherapy, biotherapy, and treatment-related drugs (includes robotic dispensing).					
<b>175</b>	Machine-readable coding (e.g., bar coding) is used at the point of care to verify chemotherapy, biotherapy, and treatment-related drug selection prior to <i>administering</i> medications.					

## Key Definitions for the Oncology Self Assessment

Key definitions are designated throughout the self assessment with **SMALL CAPITAL LETTERS**.

### **ACRONYM**

An abbreviation formed from the first letter of each major word in a phrase (e.g., ISMP stands for Institute for Safe Medication Practices).

### **ACTUAL WEIGHT**

See **WEIGHT**.

### **ADJUSTED WEIGHT**

See **WEIGHT**.

### **AREA UNDER THE CURVE (AUC)**

The amount of drug exposure or total drug concentration in plasma over a period of time, with the target **auc** usually ranging from 2 to 7.5 mg/mL x minutes. The **auc** is used primarily to determine the dose of **CARBO**platin to be administered based on the target **auc** and the patient's renal function.

### **AUTHORITATIVE COMMITTEE**

A committee empowered to make decisions related to patient medication therapy and clinical practice policies related to medication use (e.g., Pharmacy and Therapeutics Committee).

### **BATCH**

The preparation of multiple units of the same drug with the same concentration in the same diluent and final volume – at one time – that can be used for multiple patients.

### **BEHAVIORAL CHOICES**

Refers to *intentional* acts that are undertaken by the free exercise of one's judgment. Unlike human error, which is *unintentional* behavior, **BEHAVIORAL CHOICE** represents the purposeful behavior we intentionally employ while engaging in our day-to-day activities.

### **BIOLOGIC SAFETY CABINET (BSC)**

A ventilated cabinet for the compounding of sterile preparations, providing protection for personnel, the product, and the environment. It has an open front with inward airflow for personnel protection from hazardous drug exposure, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for the maintenance of product sterility, and HEPA-filtered exhausted air for environmental protection.<sup>1</sup> (See related term – **ISOLATOR**.)

### **BOARD OF TRUSTEES/DIRECTORS**

A governing body of elected or appointed individuals who have oversight over the organization.

### **BODY SURFACE AREA (BSA)**

The total surface of the human body based on height and weight that is used to calculate many chemotherapy drug doses. It is expressed as meters squared (m<sup>2</sup>).

### **CATASTROPHIC STOP**

Clinical alert in electronic systems (e.g., infusion pumps, order entry systems) that notifies the user that something is out of range or incorrect and prevents them from continuing. The alert cannot be overridden and the user has to start the process over from the beginning. (See also **HARD STOP**.)

### **CLOSED SYSTEM TRANSFER DEVICE**

A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system; a device that does not exchange unfiltered air or contaminants with the adjacent environment (e.g., Spiros, Onguard, PhaSeal). ([http://www.pppmag.com/documents/V6N5/p28\\_29\\_30\\_31.pdf](http://www.pppmag.com/documents/V6N5/p28_29_30_31.pdf))

<sup>1</sup> Definitions, USP Chapter <797> Pharmaceutical Compounding — Sterile Preparations, Revision Bulletin, 2008

## Key Definitions for the Oncology Self Assessment (continued)

### **COMPUTER SYSTEM**

Refers to any electronic system into which medication orders are entered, such as computerized prescriber order entry (CPOE) systems into which medical staff enter medication orders, pharmacy computer systems into which pharmacy staff enter or validate medication orders, and nursing computer systems into which nurses document patient care activities and medication administration.

### **CONTINUOUS INTRAVENOUS INFUSION**

Intravenous administration of a sterile fluid without interruption, over a defined period of time.

### **CYCLE**

A dose of chemotherapy/biotherapy that is repeated at regular intervals (a cycle may also be known as a “course” or a “course of therapy”). Several chemotherapy/biotherapy cycles may make up a total treatment protocol. For example, the CHOP chemotherapy protocol may consist of six cycles of treatment given every three weeks.

### **ENCOUNTER**

Any time a patient is provided with services from the organization/practice setting (e.g., a hospital admission, an office visit, a clinic visit for treatment).

### **HARD STOP**

A forcing function in the computer system, intravenous infusion device, or other technology that will not allow the practitioner to continue operation without re-entering the information. (See also **CATASTROPHIC STOP**.)

### **HEALTHCARE PRACTITIONER**

An individual with formal training who is authorized to perform specific healthcare related tasks (e.g., physician, nurse, pharmacist, pharmacy technician, healthcare aide).

### **HEALTHCARE TEAM**

An interdisciplinary group (e.g., physician, nurse, pharmacist, pharmacy technician, social worker, etc.) that collaborates to deliver and monitor patient care.

### **IDEAL WEIGHT**

See **WEIGHT**.

### **INDEPENDENT DOUBLE CHECK**

A procedure in which two individuals, preferably two licensed practitioners, separately check each component of the work process. An example would be one person calculating a medication dose for a specific patient and a second individual independently performing the same calculation (not just verifying the calculation) and matching results.

### **INSTITUTIONAL REVIEW BOARD (IRB)**

An interdisciplinary group that has been formally designated to review and monitor biomedical research involving human subjects. An IRB has the authority to approve, require modifications in, or disapprove research. The purpose of an IRB review is to assure that appropriate steps are taken to protect the rights and welfare of human subjects participating in the research. An organization can have an internal IRB, or contract with an external IRB (may also be called a Research Ethics Board [REB]).

### **INTERMITTENT INTRAVENOUS INFUSION**

Intravenous administration of a sterile fluid for a defined duration that is repeated at defined intervals.

### **INTRAVENOUS PUSH**

Intravenous administration of a small volume of sterile fluid over a short period of time, usually via a syringe.



## Key Definitions for the Oncology Self Assessment (continued)

### **ISOLATOR**

A specifically designed cabinet for compounding sterile preparations, providing protection for personnel from hazardous drug exposure, maintenance of product sterility, and protection of environmental chemical contamination. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum). Many isolators are sealed units whereby personnel prepare products by working through sealed portals with integral gloves attached to the portals. These sealed units may also be known as glove boxes. Some types of isolators require all materials inside to be gas sterilized. (See related term **BIOLOGIC SAFETY CABINET**.)

### **JUST CULTURE**

Refers to a safety-supportive model of shared accountability where healthcare institutions are accountable for the systems they design, for supporting the safe behavior choices of patients, visitors, and staff, and for responding to staff behaviors in a fair and just manner. In turn, staff are accountable for the quality of their **BEHAVIORAL CHOICES** (human error is not a **BEHAVIORAL CHOICE**) and for reporting errors and system vulnerabilities.

### **LICENSED HEALTHCARE PRACTITIONER**

An individual permitted by law to provide health care, treatment, or services without direct supervision.

### **MAXIMUM DOSE**

The dose of a medication that represents the upper limit that is normally found in the literature, protocol, and/or manufacturer recommendations. **MAXIMUM DOSES** may vary according to age, weight, diagnosis, or co-morbidity.

### **ORDER SET**

An ordering template, either pre-printed or electronic, that contains predefined information that is derived from evidence-based best practice guidelines.

### **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

PPE is equipment worn by those who handle, prepare, and administer chemotherapy/biotherapy and who handle excreta from patients who have received chemotherapy/biotherapy to minimize exposure. Examples of PPE include gloves, gowns, and eye protection.

### **PRESCRIBER**

A healthcare practitioner who is legally permitted to prescribe care, treatment, and services without direct supervision as authorized by your organization.

### **PROACTIVE RISK ASSESSMENT**

A quality improvement method that is based on the analysis of possible failures in the process, the possible consequences of the failure, and associated risk factors that may lead to the failure. Examples of **PROACTIVE RISK ASSESSMENT** tools include Failure Mode and Effects Analysis (FMEA) as well as self assessments such as this one.

### **PROTOCOL**

A defined regimen for managing a particular treatment for a specific diagnosis (includes chemotherapy/biotherapy medications and dosing guidelines, supportive treatments, and required monitoring).

## Key Definitions for the Oncology Self Assessment (continued)

### **PULLBACK METHOD**

A method used during drug preparation in which the drug is drawn into a syringe, injected into an infusion bag/container, and then the syringe plunger is “drawn back” to demonstrate the volume that was added to the container for a second individual to verify the preparation. (This is not a recommended method to verify final drug preparation.)

### **REDUNDANT (REDUNDANCIES)**

Repetitive steps that are intentionally added to a process to help detect errors.

### **ROOT CAUSE ANALYSIS (RCA)**

A team-based retrospective process for identifying the underlying causal factors that may have led to a preventable adverse event.

### **SOFT STOPS**

Clinical alerts that notify the user that something should be checked or confirmed before continuing. However, the user can easily override the alert and continue the process.

### **SPECIAL ACCESS DRUGS**

Drugs that are provided by a supplier/vendor through a restricted distribution process, often requiring government or regulatory intervention.

### **STRUCTURED PROCESS**

A defined systematic and standardized process with clearly defined steps and expected endpoints that have been agreed upon by the organization and all staff have been educated to follow.

### **SYSTEM DESIGN/REDESIGN**

Refers to the design/redesign of processes, procedures, equipment, interfaces, overall structure, and the environment or conditions under which staff work, for the purpose of satisfying specific requirements, such as patient safety. The design of a system dictates how reliable it is in terms of satisfying specific requirements.

### **TALL MAN LETTERING**

Refers to the use of mixed case letters to help draw attention to the dissimilarities of certain look-alike drug name pairs e.g., vin**CRIS**tine and vin**BLAS**tine. A list of look-alike drug names with recommended **TALL MAN LETTERING** can be found at:

<http://www.ismp.org/Tools/tallmanletters.pdf>.

### **TIME-OUT**

A formal process by which, immediately prior to a procedure, healthcare providers pause to review a standardized checklist to confirm the drug to be administered and the procedure to be performed for the patient (e.g., confirming the right patient, drug, dose, diluent, route, site, rate of administration).

### **TRANSITION OF CARE**

The movement of a patient from one level or area of care to another (e.g., moving from an intensive care unit to a general hospital unit; transferring from a hospital to a nursing home).

### **TRIGGERS**

Critical indicators (e.g., laboratory values, patient symptoms, use of antidotes for medications administered) that alert practitioners to the need for evaluation of a potential adverse event.

### **WEIGHT**

- **ACTUAL WEIGHT**

The **ACTUAL WEIGHT** of a patient without shoes or heavy clothing.

- **ADJUSTED WEIGHT**

A calculated weight based on a standard formula that considers the lipid distribution characteristics of the patient.

- **IDEAL WEIGHT**

The lean body weight of a patient, calculated using a standard formula based on height and gender.

## 2012 ISMP International Medication Safety Self Assessment® for Oncology FREQUENTLY ASKED QUESTIONS (FAQs)

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### GENERAL

**1. What if a specific self assessment item does not apply to the services provided in my organization/practice setting?**

A few of the self assessment items offer the option of “Not Applicable.” For these items “Not Applicable” can only be selected if your organization/practice setting does not provide the service. For example, if your organization/practice setting does not use radiolabeled chemotherapy/biotherapy drugs, you can answer “Not applicable” to item #92.

**2. Our health system consists of three hospitals, which all share many of the same corporate functions (e.g., Pharmacy and Therapeutics [P&T] Committee, Risk Management, Information Technology, policies and procedures). Should we complete just one assessment for all three hospitals?**

It is recommended that each hospital in a multihospital system complete the assessment individually and submit their information separately. The items in the assessment ask questions well beyond governance and policies and procedures that are in place. Each hospital will truly benefit if they complete the assessment individually and obtain their individual set of scores.

### DEMOGRAPHICS

**1. Must I answer all of the questions in the demographics section?**

All questions in the demographics section must be completed with the exception of question #23, which is optional.

**2. Are there specific guidelines available for which choice to select for certain questions in the demographics section?**

Assistance may be needed from your organization’s/practice setting’s administration for some of the demographic questions. Responses to these questions should correspond with responses your organization submits to licensing agencies, insurers, accrediting agencies, and other applications that may be required within your country.

**3. What is meant by “describe your organization/practice setting” in question #3?**

When describing your organization/practice setting, both inpatient and outpatient areas where chemotherapy and biotherapy is administered are being assessed. This includes inpatient nursing units, specialty areas (i.e., nuclear medicine, the operating room), outpatient clinics, ambulatory surgical centers, and private- or hospital-owned physician office practices. Select the category that best fits your organization/practice setting; for example, if your practice setting is a private physician office practice, you would indicate that you are an outpatient setting and indicate the number of chairs/beds in use and the percent (%) oncology.

## Frequently Asked Questions (FAQs) (continued)

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**4. What is meant by the number of doses administered per month in #9?**

When determining how to answer this question, a dose is defined as one drug anytime it is prepared for administration. This information should be accessible through your pharmacy system or medication administration log.

**5. My hospital is part of a collaborative that plans to aggregate the results of its hospital members. How do I obtain my code for question #23?**

If you are part of a participating collaborative that plans to share its aggregate data internally, within the collaborative group, please contact ISMP or ISMP Canada to obtain a collaborative-specific code, which will then be entered into the box provided in question #23. If you are not part of a collaborative that will be aggregating its results, please leave this question blank.

## SELF ASSESSMENT ITEMS

### I. Patient Information

#### Core Characteristic #1

**Item #8.**

**What is meant by “prior to preparation”?**

In this item we want to determine if chemotherapy/biotherapy agents are being prepared and sent to the infusion area before intravenous access is obtained and verified. Waiting to prepare the agents until after intravenous access is obtained and verified reduces the chance that the chemotherapy/biotherapy agents are not wasted or left in a location where they could be inadvertently administered to other patients.

#### Core Characteristic #2

**Item #11.**

**What is meant by “easily and electronically”?**

Many organizations/practice settings are utilizing electronic documentation or have essential patient information in the computer system. Practitioners caring for these patients should be able to access this information easily, without going into multiple computer systems or various screens to get the information that is needed; i.e., they should be able to access this information from their work station with little difficulty.

## Frequently Asked Questions (FAQs) (continued)

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### II. DRUG INFORMATION

#### Core Characteristic #3

**Item #23 a.**

Answer N/A (Not Applicable) if your organization/practice setting does not have inpatient oncology services.

**Item #23 b.**

Answer N/A (Not Applicable) if your organization/practice setting does not have outpatient oncology services.

#### Core Characteristic #4

**Item #37.**

Answer N/A (Not Applicable) if your organization/practice setting does not use investigational drugs.

### III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

#### Core Characteristic #5

**Item 40 a.**

Answer N/A (Not Applicable) if your organization/practice setting does not have inpatient oncology services.

**Item 40 b.**

Answer N/A (Not Applicable) if your organization/practice setting does not have outpatient oncology services.

#### Core Characteristic #6

**Item #45.**

**What is meant by “ordered in detail” when prescribing the initial cycle of chemotherapy/biotherapy orders?**

When chemotherapy/biotherapy is ordered, specific details need to be included. These are: generic name, brand name (if necessary), dose calculation, total dose, diluent, concentration, rate (infusion duration), drug sequence. If any of these items are commonly missing in chemotherapy/biotherapy orders, the organization cannot select E (fully implemented).

## Frequently Asked Questions (FAQs) (continued)

### Items #45, 46, and 47.

#### **Do prescribers have to be oncologists or board certified in oncology to prescribe chemotherapy?**

Prescribers need to have some formal training in order to write orders for chemotherapy/biotherapy for oncology and non-oncology indications. However, there are times when practitioners other than oncologists (e.g., urologists, neurologists) prescribe chemotherapy for oncology and non-oncology related conditions. As long as the prescriber has had some formal training in treating these specific conditions, then these items can be scored as being fully implemented. If general practitioners with no formal training in oncology are able to prescribe chemotherapy for oncology conditions in your organization/practice setting, then these items cannot be rated as being fully implemented (E).

### Item #60.

#### **What is meant by a list of error-prone abbreviations being established for written and electronic orders?**

The organization/practice setting has a defined list of error-prone abbreviations that are not used for drug order communication. This list is based on lists available from ISMP, ISMP Canada, or the Australian Commission on Safety and Quality in Health Care and is specifically designed to meet the needs of the organization/practice setting.

<http://www.ismp.org/Tools/errorproneabbreviations.pdf>

<http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2006-04Abbr.pdf>

[http://www.health.vic.gov.au/qum/downloads/acsqhc\\_recommendations.pdf](http://www.health.vic.gov.au/qum/downloads/acsqhc_recommendations.pdf)

## Core Characteristic #7

### Item #75.

Answer N/A (Not Applicable) if your organization/practice setting does not dispense oral chemotherapy/biotherapy drugs for patients to self-administer at home.

## Core Characteristic #8

### Item #77.

#### **When dispensing vinCRiStine, does the warning label have to be stated exactly as it is written in this item?**

This is the World Health Organization (WHO) warning and it is the preferred warning.

### Item #78 and 79.

Answer N/A (Not Applicable) if your organization/practice setting does not administer intrathecal medications.

## Frequently Asked Questions (FAQs) (continued)

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### IV. DRUG LABELING, PACKAGING, AND NOMENCLATURE

#### Core Characteristic #9

##### Item #82.

Answer N/A (Not Applicable) if medications are not prepared for or administered by the intrathecal route in your organization/practice setting.

##### Item #83 a and b.

##### **Is there a standardized format that should be used for pharmacy-generated labels?**

Many jurisdictions have requirements for information legally required on a prescription label (e.g., pharmacy name, address, phone number, patient name, drug name and manufacturer, dose, quantity dispensed, directions for use, date dispensed, etc); however they do not address how information is to be displayed on a hospital pharmacy label to optimize readability and understanding. ISMP has developed general labelling guidelines, available at: <http://www.ismp.org/tools/guidelines/labelFormats/default.asp>. Cancer Care Ontario has developed guidelines for labelling specific to oncology settings, Trudeau M, Green E, Cosby R et al. Evidence-Based Series #12-11, Patient Safety Issues: Key Components of Chemotherapy Labelling, available at: <https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=50193>

### V. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION

#### Core Characteristic #10

##### Item #91.

Answer N/A (Not Applicable) if your organization/practice setting does not use investigational drugs.

##### Item #92.

Answer N/A (Not Applicable) if your organization/practice setting does not use radiolabeled chemotherapy/biotherapy drugs.

##### Item #95.

##### **What is the definition of a commercially available standard base solution?**

Errors have occurred in compounding base solutions from raw ingredients. It is recommended that commercially available base solutions be used; e.g., If 350 mL of sodium chloride 0.9% is needed, it is recommended that it be withdrawn from a 500 mL bag that was purchased from an accredited/certified vendor, not prepared on site, even if an automated compounder is available.

##### Item #96.

Answer N/A (Not Applicable) if your organization/practice setting uses only commercially available standard base solutions.

## Frequently Asked Questions (FAQs) (continued)

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### VI. MEDICATION DEVICE ACQUISITION, USE, AND MONITORING

#### Core Characteristic #12

**Item #111.**

Answer N/A (Not Applicable) if your organization/practice setting does not use multichannel infusion pumps.

**Item #112.**

Answer N/A (Not Applicable) if your organization/practice setting does not use disposable controlled rate devices (e.g., elastomeric).

### VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS

#### Core Characteristic #13

**Item #118 a.**

Answer N/A (Not Applicable) if your organization/practice setting does not have inpatient oncology services.

**Item #118 b.**

Answer N/A (Not Applicable) if your organization/practice setting does not have outpatient oncology services.

**Item #130.**

Answer N/A (Not Applicable) if your organization/practice setting does not use **CLOSED SYSTEM TRANSFER DEVICES**.

### VIII. STAFF COMPETENCY AND EDUCATION

#### Core Characteristic #14

**Item #141.**

Answer N/A (Not Applicable) if your organization/practice setting does not provide oncology services requiring patient transfer between departments.



## Frequently Asked Questions (FAQs) (continued)

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### X. QUALITY PROCESSES AND RISK MANAGEMENT

#### Core Characteristic #17

##### Item #158.

**Does our organization/practice setting have to employ one full-time employee to review and analyze medication errors?**

This does not need to be a designated position for a full-time employee; it just means that it has to be part of someone's regular job responsibilities whether they are full-time or part-time. They can have other primary responsibilities, but this should be included as a specific function in their job description.

#### Core Characteristic #18

##### Item #167.

**What is meant by "verification"?**

This does not mean that the pharmacist or nurse needs to weigh the patient or measure the patient's height again. It means that if there is ANY question that these measurements are not accurate (i.e., have been entered or documented incorrectly) that a reasonableness check or visual check is then done. We have received error reports where the height was entered as the weight and the weight was entered as the height, resulting in an overdose.