TITLE

CONSENT TO TREATMENT/PROCEDURE(S)

SCOPE

Provincial

APPROVAL AUTHORITY

Executive Leadership Team

SPONSOR

Vice President, Health Professions & Practice;
Associate Chief Medical Officer, Quality & Medical Affairs

PARENT DOCUMENT TITLE, TYPE AND NUMBER

Not applicable

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms — please refer to the Definitions section.

If you have any questions or comments regarding the information in this document, please contact the Policy & Forms Department at policy@ahs.ca. The Policy & Forms website is the official source of current approved policies, procedures, directives, standards, protocols and guidelines.

OBJECTIVES

- To facilitate an informed consent process within Alberta Health Services (AHS) that reflects good practice, contributes to patient safety, and enhances the patient experience.

- To facilitate a fair, respectful process for informed consent that is achieved consistently across all care areas within AHS.

- To facilitate compliance with applicable law.

PRINCIPLES

The principle of respect for persons is foundational within this policy and demonstrated by patients being supported in determining what happens to their own bodies, in keeping with their own values and beliefs. Where patients cannot make their own decisions, respect for persons is upheld by recognizing the decision-making role of an appropriate alternate decision-maker.

Informed consent:

- requires capacity;
- shall be informed;
- shall be specific;
- shall be voluntary;
- requires understanding; and
• shall be documented.

On an exceptional basis, patient-informed consent decisions can be overridden in accordance with legislation such as the Mental Health Act and the Public Health Act.

The most responsible health practitioner (MRHP) providing the treatment/procedure(s) to a patient has a duty to obtain informed consent.

AHS is committed to providing continuing education for all personnel to implement this policy and the subsequent procedures.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Informed Consent is Required

1.1 Before providing a specific treatment/procedure(s) or plan of treatment/procedure(s), the MRHP shall obtain express informed consent or implied informed consent from the patient, unless a valid exception to informed consent applies (see Section 5 below).

1.2 The MRHP is responsible for determining the most appropriate method of obtaining informed consent (express or implied).

1.3 All consent, whether express or implied, shall be informed.

1.4 Implied informed consent may be presumed in (but is not limited to) circumstances where the patient presents voluntarily for an examination, investigation, or minor or less invasive treatment/procedure(s) which the MRHP determines does not require express informed consent.

a) The MRHP shall be satisfied that the circumstances or the actions of the patient imply permission for the examinations, investigations, and treatment/procedure(s) proposed.

b) If there is any doubt that there is implied informed consent, the MRHP shall obtain express informed consent from the patient.

c) Implied informed consent is encouraged to be documented by the MRHP in the patient’s health record.

1.5 When the MRHP determines that express informed consent is required to evidence the patient’s informed consent to the treatment/procedure(s):
POLICY

CONSENT TO TREATMENT/PROCEDURE(S) January 16, 2020 PRR-01

a) verbal consent shall be documented by the MRHP in the patient's health record; or
b) written (signed) consent shall be documented by the MRHP through obtaining the signature of the patient on the applicable consent form (see Section 1.7 below), which shall then be attached to the patient's health record. Where a consent form is used, documentation in the patient’s health record regarding the informed consent discussion is also recommended.

1.6 Notwithstanding Section 1.2 above, written (signed) consent shall be obtained for:

a) the transfusion of blood and blood products;
b) surgery;
c) invasive investigative procedures;
d) human tissue and organ donation; and
e) medical assistance in dying, consistent with the AHS Medical Assistance in Dying Policy.

1.7 The following consent forms shall be used in the following situations or any other treatment/procedure(s) for which the MRHP deems written (signed) consent to be appropriate:

a) The AHS Consent to Surgery or Invasive Procedure Form should be used for all surgical or invasive procedures including endoscopy or cardiac catheterization. This form includes sections about possible transfusion and testing for blood-borne viruses in the event of needle-stick injuries or body fluid splashes as well as for the retention of tissue and the involvement of trainees.

b) The AHS Consent to Treatment Plan/Intervention or Procedure Form should be used for lesser or non-invasive procedures or treatment plans and interventions that are deemed to reach the threshold of requiring written (signed) consent such as a bedside procedure or blood product transfusion.

c) The AHS Emergency Health Care: Documentation of Exception to Consent Form should be used in situations where it is deemed that a procedure, which would otherwise require written (signed) consent, is occurring in an emergency situation where it is not possible to do so.

1.8 Informed consent may be obtained in the MRHP’s community office rather than at the applicable Alberta Health Services (AHS) setting where the patient will be receiving the treatment/procedure(s). Any completed consent forms shall then
be forwarded to the applicable AHS setting where the patient will be receiving the treatment/procedure(s).

2. **Accountability**

   2.1 The accountability to obtain informed consent shall rest with the MRHP who is providing the specific treatment/procedure(s).

   2.2 The MRHP remains accountable for the informed consent process when one (1) or more than one (1) health care provider is involved in providing the treatment/procedure(s).

   2.3 The MRHP is responsible for confirming the validity of informed consent prior to the delivery of the treatment/procedure(s).

   2.4 For programs that offer multiple treatment/procedure(s), each MRHP is accountable for the informed consent process related to the treatment/procedure(s) they are providing.

3. **Required Components of Informed Consent**

   3.1 Capacity:

      a) The MRHP is responsible to conduct initial assessment of the patient for determination of capacity to make treatment and care decisions.

         (i) Where the MRHP cannot complete an assessment of the patient for the determination of capacity to make treatment decisions, the MRHP shall ensure assessment of the patient’s capacity by an appropriate clinical expert (refer to list of approved capacity assessors).

      b) An adult patient is presumed to have capacity to make treatment/procedure(s) decisions unless the patient is determined to lack capacity.

         (i) When an adult patient lacks capacity to consent to a treatment/procedure(s), the authority of a co-decision-maker or an alternate decision-maker shall be recognized in accordance with the AHS Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity Procedure.

         (ii) Capacity for a minor patient shall be determined in accordance with the AHS Consent to Treatment/Procedure(s): Minors / Mature Minors Procedure.

      c) The MRHP shall be satisfied that the patient has the capacity to make each treatment/procedure(s) decision.
(i) If a patient is considered to have capacity and consents to the proposed treatment/procedure(s), they may be treated.

(ii) A patient’s capacity can change depending on changes to their mental and physical health.

(iii) The determination of capacity shall relate to each specific treatment/procedure(s) or plan of treatment/procedure(s).

(iv) Informed consent shall be obtained prior to the administration of any medication that may significantly affect the patient’s capacity to make an informed decision (i.e., analgesic, narcotic, or anaesthetic).

(v) A patient may have capacity even if they are unable to communicate verbally. Communication with the patient shall be facilitated by any means that enables understanding (see Section 3.5 below).

(vi) The patient’s choice to make decisions based on their values and beliefs shall be supported, subject to exceptions (see Section 5 below).

3.2 Informed:

a) The MRHP shall ensure all necessary information has been provided to the patient so that the patient can make an informed decision about the treatment/procedure(s). Necessary information shall include but is not limited to:

   (i) the condition for which the treatment/procedure(s) is proposed;

   (ii) the treatment/procedure(s) plans/interventions and/or list of agreed upon treatment/procedure(s), that are clinically indicated and approved for the condition;

   (iii) the potential risks and benefits of the proposed treatment/procedure(s);

   (iv) information applicable to the patient’s particular circumstances or as specifically requested by the patient;

      • If the patient alerts the MRHP of particular circumstances that might affect the information the patient would want for their treatment/procedure(s), the MRHP shall be responsible for addressing those particular circumstances with further information as requested by the patient.

   (v) alternatives to the proposed treatment/procedure(s);
(vi) the potential consequences of both providing consent or refusing to provide consent for the proposed treatment/procedure(s); and

(vii) who will perform the treatment/procedure(s) and who may provide assistance, including whether the treatment/procedure(s) will include health care providers in training (i.e., residents, students).

3.3 Specific:

a) The provision of informed consent shall relate to each specific treatment/procedure(s) or a plan of treatment/procedure(s).

b) Treatment/procedure(s) that:

(i) are in addition to the treatment/procedure(s) already consented to;
(ii) are different from the treatment/procedure(s) consented to;
(iii) were unanticipated at the time informed consent was obtained;
(iv) may be convenient to do; or
(v) may be beneficial to the patient,

shall not be performed without obtaining further informed consent, unless a valid exception to informed consent applies (see Section 5 below).

c) New informed consent shall be obtained when one (1) or more of the following occurs:

(i) the patient’s condition has materially changed;
(ii) the medical knowledge about the patient’s condition or the treatment/procedure(s) available has materially changed;
(iii) when the treatment/procedure(s) for the patient changes;
(iv) the previously given consent and/or any portion of the previously given consent has been withdrawn (see Section 4 below); and
(v) the patient has refused the involvement of particular individuals in their treatment/procedures(s) (i.e., medical students).

d) If the previous informed consent was evidenced using a consent form, then the new or subsequent informed consent should also be evidenced using a consent form.
3.4 Voluntary:

a) The patient shall have the opportunity, without undue influence, to accept or refuse a treatment/procedure(s).

b) As time permits in the clinical circumstance, informed consent discussions shall occur when the patient has a reasonable opportunity to reflect on the decision and ask questions.

c) When appropriate to do so, informed consent discussions should not take place in the operating room or the operating room environment.

d) The patient shall be given an opportunity to take the time required to reflect on the information and to consult with whom they choose prior to making a decision.

e) A patient’s decision to accept or refuse a treatment/procedure(s) shall not prejudice their access to ongoing or future health care.

3.5 Understanding:

a) The MRHP accountable for the informed consent process shall:

   (i) provide the patient with the opportunity to ask questions;

   (ii) provide responses to the questions asked by the patient; and

   (iii) ensure the patient has understood the information sufficiently to proceed with the informed consent discussion.

b) The informed consent discussion is a shared process between the patient and the MRHP, resulting in the patient’s decision to accept or refuse the proposed treatment/procedure(s).

c) The MRHP shall communicate with the patient in a manner that supports the patient’s ability to understand and shall address all communication barriers including, but not limited to:

   (i) hearing;

   (ii) sight;

   (iii) language;

   (iv) culture;

   (v) literacy;

   (vi) level of education;
(vii) level of anxiety and stress; and
(viii) environmental factors, including location of discussion.

d) If the patient is having difficulty understanding the discussion or reading and completing the consent form (if applicable), the discussion and contents of the consent form shall be read and explained to the patient in the presence of a witness and with the assistance of an interpreter, as necessary. Documentation of this process is recommended. The MRHP may allow, at the patient’s request, their family to accompany the patient and offer their assistance to help the patient to understand or demonstrate an understanding of the information provided.

4. Refusal of Treatment/Procedure(s) and Withdrawal of Informed Consent

4.1 Subject to situations in which a treatment/procedure(s) is ordered in accordance with applicable legislation, an adult patient with capacity to consent to a treatment/procedure(s) may at any time:

a) refuse to consent to all or a portion of a proposed treatment/procedure(s); or

b) withdraw previously given informed consent to any or all of the treatment/procedure(s) at any time prior to or during the treatment/procedure(s).

4.2 Subject to situations in which a treatment/procedure(s) is ordered in accordance with applicable legislation, an adult patient with capacity may refuse to consent to a treatment/procedure(s) or withdraw informed consent on any grounds prior to the start of the treatment/procedure(s), even when it is clear that the treatment/procedure(s) is necessary to preserve their life or health. In such an instance, the treatment/procedure(s) shall not be carried out, even if failure to provide such a treatment/procedure(s) may result in the patient’s death.

a) The alternate decision-maker for an adult patient lacking capacity may refuse a treatment/procedure(s) or withdraw previously given informed consent in accordance with the AHS Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity Procedure.

b) A mature minor or a minor’s legal representative may refuse a treatment/procedure(s) or withdraw previously given informed consent in accordance with the AHS Consent to Treatment/Procedure(s): Minors / Mature Minors Procedure.

4.3 After a treatment/procedure(s) has been commenced, the MRHP shall stop providing the treatment/procedure(s) immediately upon the withdrawal of the informed consent and shall revisit the informed consent process with new or additional information that should be shared with the patient.
a) If the termination of the treatment/procedure(s) will result in immediate and serious risk to the patient, the MRHP may be required to continue with the originally consented to treatment/procedure(s) to the extent required to limit the immediate and serious risk to the patient.

4.4 Where a patient refuses to consent to a treatment/procedure(s) or withdraws previously given informed consent, the MRHP shall explain the potential risks and consequences of the refusal or withdrawal of informed consent, without undue influence.

a) This explanation can be witnessed by a second health care professional to confirm patient identity and confirm the discussion occurred.

b) The MRHP shall document on the patient’s health record:

(i) the refusal or withdrawal of informed consent;

(ii) the circumstances of the refusal, including the patient’s reasons for withdrawing informed consent or refusing the treatment/procedure(s);

(iii) a summary of the discussion with the patient about the patient’s clinical condition, the planned treatment/procedure(s) or interventions, the expected outcomes, material risks, and potential consequences of withdrawing informed consent or refusing the treatment/procedure(s);

(iv) the outcome of the discussion;

(v) the presence of witnesses, if any; and

(vi) where written (signed) informed consent was previously given, withdrawal of consent shall be documented in the ‘withdrawal’ section of the consent form.

4.5 The patient may provide informed consent again at any time following a subsequent informed consent discussion.

4.6 Adult patients who carry written and signed statements refusing the infusion of blood products shall have their wishes respected. This includes situations where the patient presents to an AHS setting for emergency health care.

5. Exceptions to Informed Consent

5.1 Emergency Health Care Exception:

a) For adult patients:
(i) If an adult patient requires emergency treatment/procedure(s) but the adult lacks the capacity to provide informed consent or refuses informed consent due to altered consciousness from trauma, drugs, alcohol, or any other cause, or where informed consent cannot be immediately obtained from the adult’s alternate decision-maker, emergency health care may be provided by a MRHP:

- only where it is immediately necessary to preserve the patient’s life, prevent serious physical or mental harm to the patient, or to alleviate serious pain; and

- where there is no knowledge that the patient would have objected to the treatment/procedure(s).

- If a Physician is not available, a Nurse Practitioner or Registered Nurse may initiate emergency health care as per their scope of practice.

(ii) The MRHP shall document that an emergency situation exists by completing the relevant section of the AHS Emergency Health Care: Documentation of Exception to Consent Form. In all possible situations, a second Physician or MRHP shall confirm the existence of the emergency situation, although it is recognized that in rural settings there may not always be a second Physician available.

- If a second Physician is not available, a Nurse Practitioner or Registered Nurse may confirm the existence of the emergency situation and document the same on the AHS Emergency Health Care: Documentation of Exception to Consent Form.

- Resident Physicians are not permitted to provide a written opinion to confirm the criteria for emergency health care.

(iii) The details of the emergency situation and all treatment/procedure(s) decisions shall be documented in the patient’s health record. All reasonable efforts shall be made to contact the patient’s alternate decision-maker or next of kin, as appropriate, to advise that emergency treatment/procedure(s) was provided.

(iv) The Emergency Health Care Exception is only valid during the emergency situation. All future treatment/procedure(s) provided outside of the emergency situation shall require informed consent.
b) For minor patients:
   (i) The applicability of the Emergency Health Care Exception for a minor patient shall be determined in accordance with the AHS Consent to Treatment/Procedure(s): Minors / Mature Minors Procedure.

5.2 Exceptional Circumstances:
   a) The requirement for informed consent may be overridden by a warrant, subpoena, court order, or applicable legislation (e.g., a review panel’s treatment order under the Mental Health Act, orders under the Public Health Act, orders under the Mandatory Testing and Disclosure Act, etc.).

6. Documentation

6.1 The MRHP is responsible for ensuring appropriate documentation of the informed consent process and outcomes in the patient’s health record. Specifically, the following outcomes shall be documented:
   a) agreement with informed consent to the treatment/procedure(s);
   b) refusal of the treatment/procedure(s) (refer to Section 4 above); and
   c) withdrawal of consent previously given (refer to Section 4 above).

6.2 All relevant legal documents including, but not limited to, court orders, warrants, subpoenas, personal directives, capacity assessments, and evidence of the formal status of alternate decision-makers, shall be documented on the patient’s health record.

6.3 While the requirements for documentation outlined in Section 6.1 above are met by appropriately filling in the applicable consent form where written (signed) consent has been deemed necessary, documentation in the patient’s health record regarding the consent discussion is recommended.

6.4 Completed consent forms required for treatment/procedure(s) may be faxed or scanned (refer to the AHS Transmission of Information by Facsimile or Electronic Mail Policy). When possible, and at the earliest opportunity, the original consent form shall be obtained and placed on the patient’s health record.

6.5 When an interpreter is used to assist in obtaining consent, the interpreter shall complete the relevant documentation on the consent form.
   a) The MRHP shall follow up to ensure the consent form has been completed as required.

6.6 A blind or disabled person’s ‘mark’ is recognized as a valid signature on the consent form.
6.7 Witness documentation of informed consent:

a) A written (signed) consent form should be witnessed.

b) Any person, other than a relative of the patient, the MRHP, or the interpreter for the patient, may witness the signing of a consent form.

   (i) Before acting as a witness or signing the consent form as a witness, confirmation of the patient’s identity by the witness shall be required.

   (ii) If the signee is not the patient, the witness shall request to see a form of the signee’s identification and confirm that the person making a mark on behalf of the patient has been asked to do so by the patient.

c) Witnessing a consent form indicates only that the witness observed the consent form being signed and is not evidence of the consent process.

d) In the event that the patient expresses doubt about the consent process and/or requests further explanation, the witness shall not sign the consent form and the MRHP shall be notified.

**DEFINITIONS**

*Adult* means a person aged 18 years and older.

*Agent* means the person(s) named in a personal directive who can make decisions on personal matters according to the wishes expressed by the patient.

*Alberta Health Services (AHS) setting* means any environment where treatment/procedures and other health services are delivered by, on behalf of or in conjunction with, Alberta Health Services.

*Alternate decision-maker* means a person who is authorized to make decisions with or on behalf of the patient. These may include, specific decision-maker, a minor’s legal representative, a guardian, a ‘nearest relative’ in accordance with the *Mental Health Act* (Alberta) or an agent in accordance with a personal directive or a person designated in accordance with the *Human Tissue and Organ Donation Act* (Alberta). This also includes what was previously known as the substitute decision-maker.

*Capacity* means the ability for the patient to 1) understand the nature, risks, and benefits of the procedure and the consequences of consenting or refusing; and 2) understand that this explanation applies to them.

*Consent form* means an Alberta Health Services approved form of documentation that can be used to provide evidence of the outcome of the consent process, that is, agreement to or refusal of a treatment/procedure.
Express informed consent means direct, explicit agreement to undergo treatment/procedure(s), given either verbally or in writing (signed).

Family means one or more individuals identified by the patient as an important support, and who the patient wishes to be included in any encounters with the health care system, including, but not limited to, family members, legal guardians, friends, and informal caregivers.

Guardian means, where applicable:
For a minor:
   a) A guardian as defined by the Family Law Act (Alberta), a divorced parent with custody of the minor, or a person appointed pursuant to a will, personal directive, court order, agreement or by authorization of legislation (e.g., Child, Youth and Family Enhancement Act [Alberta]).

For an adult:
   a) An individual appointed by the Court in accordance with the Adult Guardianship and Trusteeship Act (Alberta) to make decisions on behalf of the adult patient when the adult patient lacks capacity.

Health care professional means an individual who is a member of a regulated health discipline, as defined by the Health Disciplines Act (Alberta) or the Health Professions Act (Alberta), and who practises within scope and role.

Health care provider means any person who provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers and other persons acting on behalf of or in conjunction with Alberta Health Services.

Health record means the collection of all records documenting individually identifying health information in relation to a single person.

Implied informed consent means consent inferred from the patient’s or alternate decision-maker’s (if applicable) actions and surrounding circumstances.

Informed consent means the patient’s agreement (or alternate decision-maker) to undergo a treatment/procedure after being provided, in a manner the patient can understand, with the relevant information about the nature of the treatment/procedure(s), its benefits, potential risks and alternatives, and the potential consequences of refusal.

Informed consent process means a discussion or series of discussions and interactions that may occur over a period of time between the most responsible health practitioner and patient or their alternate decision-maker (if applicable) including: i) the determination of capacity, as necessary, ii) the provision of relevant information, iii) the verification of understanding, iv) the decision-making and v) documentation of the consent process and outcome.

Legal representative means the following in relation to a minor, as applicable:
   a) guardian; or
b) nearest relative as defined in the Mental Health Act (Alberta), who has the authority to consent to treatment for a minor formal patient or minor who is subject to a Community Treatment Order.

Mature minor means a person aged less than 18 years, who has been assessed and determined as having the intelligence and maturity to appreciate the nature, risks, benefits, consequences, and alternatives of the proposed treatment/procedure(s), including the ethical, emotional, and physical aspects.

Minor means a person aged less than 18 years.

Most responsible health practitioner (MRHP) means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Alberta Health Services to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

Patient means all persons, inclusive of residents and clients, who receive or have requested health care or services from Alberta Health Services and its health care providers. Patient also means, where applicable:
   a) a co-decision-maker with the person; or
   b) an alternate decision-maker on behalf of the person.

Personal directive means a written document in accordance with the requirements of the Personal Directives Act (Alberta), in which an adult names an agent(s) or provides instruction regarding their personal decisions, including the provision, refusal, and/or withdrawal of consent to treatments/procedures. A personal directive (or part of) has effect with respect to a personal matter only when the maker lacks capacity with respect to that matter.

Physician means a person licensed in independent practice and in good standing with the College of Physicians and Surgeons of Alberta pursuant to the Health Professions Act (Alberta).

Specific Decision-Maker means a nearest relative who may be selected from a hierarchy of relatives to make a specific decision on behalf of the patient according to the Adult Guardianship and Trusteeship Act.

Treatment/procedure(s) means a specific assessment, treatment, investigational procedure(s), or series of treatments/procedures planned to manage a clinical condition; these can be presented as a treatment plan/intervention.
POLICY

CONSENT TO TREATMENT/PROCEDURE(s)

January 16, 2020

PRR-01

REFERENCES

- Alberta Health Services Governance Documents:
  - Consent to Mental Health Treatment/Procedure(s): Formal Patients and Persons Subject to Community Treatment Orders Under the Mental Health Act Policy (#PRR-01-04)
  - Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity Procedure (#PRR-01-02)
  - Consent to Treatment/Procedure(s): Deceased Donation of Human Organs and Tissues Policy (#PRR-01-05)
  - Consent to Treatment/Procedure(s): Minors / Mature Minors Procedure (#PRR-01-03)
  - Medical Assistance in Dying Policy (#HCS-165-01)
  - Transmission of Information by Facsimile or Electronic Mail Policy (#1113)

- Alberta Health Services Forms:
  - Consent and Declaration for Treatment/Procedure (on Behalf of a Formal Patient or Person Subject to a Community Treatment Order who lacks capacity) Form (#09565)
  - Tissue and/or Organ Donation Consent (Human Tissue and Organ Donation Act of Alberta) Form (#09816)
  - Consent to Surgery or Invasive Procedure Form (#18628)
  - Consent to Treatment Plan/Intervention or Procedure Form (#09741)
  - Emergency Health Care: Documentation of Exception to Consent Form (#18629)

- Non-Alberta Health Services Documents:
  - Adult Guardianship and Trusteeship Act (Alberta)
  - Child, Youth and Family Enhancement Act (Alberta)
  - College of Physicians and Surgeons of Alberta: Standards of Practice (Alberta)
  - Family Law Act (Alberta)
  - Health Information Act (Alberta)
  - Health Professions Act (Alberta)
  - Human Tissue and Organ Donation Act (Alberta)
  - Mandatory Testing and Disclosure Act (Alberta)
  - Mental Health Act (Alberta)
  - Personal Directives Act (Alberta)
  - Protection for Persons in Care Act (Alberta)
  - Protection of Children Abusing Drugs Act (Alberta)
  - Public Health Act (Alberta)

VERSION HISTORY

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<tr>
<td>August 01, 2011</td>
<td>Revised</td>
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<tr>
<td>February 27, 2012</td>
<td>Non-substantive change</td>
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