5.29.4.1 Responsibility for treating recipient adverse events shall be defined. Standard 7.3.2 applies.

5.29.5 Records of Administration

Records of administration shall include:
1) Unique product identifier(s).
2) Product type.
3) Name and identifier(s) of the intended recipient.
4) Medical order for administration.
5) Confirmation of recipient and product identity before administration.
6) Names and/or identifiers of persons who administered the product.
7) Dates and times of product administration initiation and completion.
8) All administration information, including the patient’s vital signs and the time of all recorded events.
9) Whether any adverse events occurred, including a reference to the appropriate documentation of adverse event forms.
10) Records of appropriate notification if an adverse event occurred.
11) Critical steps related to product administration shall be entered into the permanent medical record by the ordering or administering physician according to facility-defined protocol. An anesthesiology record (if anesthesia is required) shall become part of the permanent medical record.

5.29.6 Recipient Records

Recipient records shall include the following:
1) Unique patient identification.
2) Medical and surgical history and physical examination.
3) Signed informed consent for administration of the cell therapy product.
4) Unique cell therapy product identifier(s).
5) If applicable, interpretation of tests for infectious disease markers.
6) If applicable, interpretation of ABO and other red cell antigen and Rh typings and, for allogeneic recipients, documentation of:
   a) The detection and identification of unexpected red cell antibodies.
   b) Assessment of blood grouping compatibility between the intended donor and recipient.
7) Documentation of HLA typing results, if indicated.

5.29.7 The facility shall have policies, processes, and procedures regarding the discharge and follow-up of patients after the administration procedure.

5.30 Postadministration Monitoring
The facility shall have policies, processes, and procedures for patient follow-up, including the collection of outcome data following the administration of cellular therapy products. This shall include any immediate or late adverse event suspected to be linked to the cellular therapy product.
### Reference Standard 5.8.1A—Requirements for Labeling of Cellular Therapy Products

(For labeling of regulated investigational products or licensed products, Standards 5.8.1.1 and 5.8.1.2 apply.)

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Element</th>
<th>Completion of Procurement</th>
<th>In-Process Label</th>
<th>Completion of Processing</th>
<th>Distribution and Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Unique alpha and/or numeric identifier of the product</td>
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<tr>
<td>2</td>
<td>Name of the product and modifiers</td>
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<td>3</td>
<td>Donor identifier or name</td>
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<tr>
<td>4</td>
<td>Date of procurement</td>
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<tr>
<td>5</td>
<td>Time of completion of procurement (time zone, if applicable)</td>
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</tr>
<tr>
<td>6</td>
<td>Name of procurement facility/donor registry</td>
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<td>7</td>
<td>Approximate product volume or weight (if applicable)</td>
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<td>8</td>
<td>Names/volumes of anticoagulants and other additives (if applicable)</td>
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<td>Recipient name and/or identifier (if known)</td>
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<td>Expiration date and time (if applicable)</td>
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<td>Red cell compatibility (if applicable)</td>
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</tr>
</tbody>
</table>

^1 Completion of Procurement includes: Procurement, Labeling, and Distribution.

^2 Distribution and Issue includes: Distribution, Issue, and Release.

^3 Name of the product and modifiers may be applicable to licensed products.

^4 Donor identifier or name may be applicable to regulated investigational products.

^5 Additional information may be required for certain products.

^6 Time of completion of procurement includes time zone, if applicable.

^7 Expiration date and time includes time zone, if applicable.