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**Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Metals and Ceramics Division**

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## 1. PURPOSE

To describe the requirements for controlling and accomplishing activities that affect quality, safety, performance, maintenance, and reliability of experiments, equipment, and services through the graded use of written documents.

## 2. SCOPE

This administrative procedure applies to the control of documentation for experimental, developmental, or production activities within the Metals and Ceramics (M&C) division.

## 3. REQUIREMENTS

Standards-Based Management System (SBMS), *Subject Area: Internal Operating Procedures* ( <http://sbms.ornl.gov.sbmsearch/subjarea/iop/sa.cfm> )

## 4. REFERENCES

ORNL SBMS Subject Area “[Internal Operating Procedures](#)”  
ORNL [Quality Assurance Program Description](#)

## 5. RESPONSIBILITIES

**5.1 Group Leader** - Establishes the need for, and level of control of, documentation within his/her group. This includes the need for standard operating guidelines, procedures, drawings, technical notebooks, operating logs, checklists, and other operational documentation. A suggested list of potential controlling documentation is provided in Appendix A, *Listing of Potential Controlling Documentation*.

The level of implementation and control of these documents will depend on:

- environmental, safety, health, and quality factors associated with group laboratory activities;
- explicit requirements (if any) of project or program customers funding group work; and
- group leader’s judgment concerning the need for formal documentation.

Each group leader has the responsibility for ensuring necessary documents are in place. It is also his/her responsibility to ensure that documentation is kept current.

**5.2 Quality Manager or Quality Assurance Specialist (QAS)** –Assists staff in ensuring that controlling documentation meets division/ sponsor requirements.

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**5.3 Staff Member** - Ensures work meets the requirements identified in work controlling documents such as guidelines, procedures, and drawings.

## **6. INSTRUCTIONS, PROCEDURES, DRAWINGS, AND RELATED DOCUMENTS**

### **6.1 Procedures, Guidelines, Specifications, Checklists, And Other Documents**

A listing of documentation that may be considered appropriate in controlling work deemed necessary by each group leader, project engineer, or cognizant program manager is included in Appendix A, *Listing of Potential Controlling Documentation*. Control of the procedures, guidelines, specifications, checklists, and other documents is described below.

#### **6.1.1 Technical Data, Technical Notebooks**

General use of technical notebooks and the data contained therein is covered in the Standards-Based Management System (SBMS), in Records Management (<http://sbms.orn.gov/sbmsearch/subjarea/recmgmt/notebook.cfm>), in the Subject Area for Technical Notebooks. This document provides instructions and guidelines for notebook content requirements, entry time and date requirements, equipment descriptions or instructions, calibration records, initialing/signing requirements, and other associated information.

#### **6.1.2 Procedures & Guidelines**

##### **6.1.2.1 Procedures/Guidelines, General Content, Format, and Controls**

1. Identification of Instructions as Procedures or Guidelines is dependent on use.
  - An instruction document will only be identified and labeled a *procedure* if it is to be strictly followed with no deviation from the steps or the order of sequence of the steps described. Certain types of activities will – in most cases – require procedures because of the risks associated with their conduct. Examples include the operation of interlocked equipment such as large presses and other high-hazard equipment with personnel safety considerations, activities conducted under the purview of the Price-Anderson Amendments Act, and use of X-ray producing devices. The Division QAS or members of the Research Support group should be consulted if group leaders or staff are unsure of what documents are necessary to satisfactorily control work.
  - Instructional documents that do not require step-by-step compliance are called *guidelines*. Guidelines allow personnel in a research environment to make use of written documents that are not overly prescriptive. The

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minimum requirements in a guideline are spelled out using the verbs *shall* and *will*.

2. Procedures/Guidelines are developed when there is a need to:

- Address the complexity or hazards of the operation. Specific instructions are needed to ensure environmental, safety, or health issues are addressed.
- Ensure the desired outcome for important activities.
- Ensure the reproducibility of results.
- Consolidate pertinent operational information dispersed throughout a manual(s) into a concise usable form.

**NOTE:** If a manual contains well-prepared, step-by-step instructions for operating a piece of equipment or system, there may be no reason to write any other type of operating document.

- To provide a consistent method for training on a piece of equipment or for a particular operation.

**NOTE:** The scope of a procedure/guideline may cover a particular piece of equipment or may cover a process covering the use of several pieces of equipment.)

- To describe operating restrictions (operating restrictions may be identified through the Research Safety Summary [RSS]).
- Provide guidance for plausible emergency situations, when signage is not enough (e.g., emergency shutdowns when placing the equipment in safe configuration is necessary).

### 6.1.2.2 Format

Appendix B, *Procedure/Guideline Outline, Format & Content*, provides specific content, format and section/paragraph numbering information.

### 6.1.2.3 Review and Approval

The required reviewers for procedures and guidelines are:

- Author
- Project Leader or Principal Investigator (if other than author and if applicable)
- Group Leader
- Division Safety Officer (DSO), (except administrative procedures)
- Radiation Control Officer (RCO), (if procedure/guideline involves radiation)

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- Price Anderson Program Officer (PPO), (if procedure/guideline involves radiation)
- Quality Assurance Specialist

**Note:** Reviews, external to the division, may be required depending on the type and scope of the document or the unique programmatic requirements imposed by the sponsor

1. Availability of Procedures/Guidelines

- A working copy of each procedure shall remain in close proximity to the equipment or process operation to which it applies.
- Each group shall also maintain a central file and numbering system (see Appendix B) for procedures and guidelines.
- The group leader, or designee, is responsible for ensuring that the latest copy of a procedure or guideline is maintained in the work area. Copies of obsolete procedures/guidelines shall be kept on file (archived). Groups are required to maintain two copies of current procedures; one in the group leader's (electronic storage is adequate) files and the other on the equipment or in the area where the procedure is used. If a third copy is maintained, the owner shall ensure that the copy being used is current.

2. Permanent Changes to Procedures/Guidelines

- A procedure/guideline shall be updated any time a process or operation changes significantly. Examples of significant changes include a new or different hazard that must be addressed, equipment or process alterations that require changes in instructions, or a change in sponsor requirements. All procedures/guidelines will be reviewed for continued applicability at least once every five (5) years. The review shall be documented by use of a re-review page as the last page of the document. A procedure/guideline is valid for five years after its effective date.
- A procedure/guideline that is no longer needed shall be marked *OBSOLETE* on any remaining copies. The group leader's copy shall be maintained as a record copy and any working copy should be destroyed.

3. Temporary Changes to Procedures/Guidelines

A procedure/guideline may be changed or *redlined* for immediate use. For a redline procedure/guideline, both copies (group leader's record copy and the working copy) shall be marked up. Additionally, the following applies:

- Additional text shall be legible and written on the same page(s) to which the change applies,

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- Removed text shall be lined through with a single line,
- All changes shall be initialed and dated, with the principle investigator's and program manager's or group leader's initials,
- The group leader or his designee shall ensure that all users of the redlined document are provided with the updated version and that all obsolete copies are removed from the work area,
- Redline changes, unless clearly marked for one time use only, shall be incorporated into a revision to the permanent procedure/guideline within six (6) months of redline approval.

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4. Mentoring

In some instances it may be very difficult to write a procedure or guideline for a piece of equipment or operation. The operation may be highly complex with a resulting dependence on the qualifications developed over several years of experience by a few or in some cases, a single individual.

- In this case, mentoring by the identified expert, with the group leader's authorization, will suffice to ensure safe, effective equipment/ process operations.
- To counter the lack of established instructional documentation, formal paperwork should be prepared outlining the qualifications of the individual(s). This way access to the equipment or operation can be severely restricted to only that individual(s).
- A justification should also be prepared, and on file, detailing the reasons a procedure/guideline will not be written. This may all be covered in a single memo to file.
- This approach is **not** a substitute for procedures/guidelines and should be used sparingly.

**6.1.3 Experimental Plans, Test Plans, Fabrication Plans, Checklists, Travelers, and Other Documents**

These types of documents are used in specific situations mandated by a sponsor's requirements. They will contain, directly or by reference to other procedures or documents, any information (e.g., safety, calibration, maintenance, reliability, training), necessary to ensure a safe and successful operation or activity. They shall also be reviewed, approved, and distributed according to the requirements of the program or project for which they are written. Appendix C, *Suggestions for Preparing Specifications, Checklists, Travelers*, provides guidance.

The required reviewers for experimental plans are:

- Author
- Principal Investigator or Project Leader
- Group Leader

The required reviewers for fabrication plans or travelers are:

- Author
- Project Leader or Principal Investigator
- Group Leader
- Quality Assurance Specialist

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#### 6.1.4 Procurement Specifications

Procurement specifications shall list any and all of the attributes that the item(s) (to be procured) should possess to do the job for which it is intended. Any warranties, manuals, inspections, tests, service requirements, certifications, acceptance inspection/ tests, or other considerations are spelled out in the specification. Appendix C also provides some guidance on procurement specification preparation.

The minimum required reviewers for procurement specifications are:

- Author
- Project Engineer or Principal Investigator
- Quality Assurance Specialist

Examples of previously-written procurement specifications can be obtained from the M&C Administrative and Engineering Services (Procurement) group or from the M&C QA Office. The QA Office can also provide guidance concerning individual procurement specifications and associated requirements to ensure success. Additional information concerning procurement issues and documents can be found in the SBMS, *Subject Area: Purchasing Supplies & Services* ( <http://sbms.ornl.gov/sbms/SBMsearch/subjarea/procurement/prodes.cfm> ).

#### 6.1.5 Operator Aids

An operator aid is approved, posted information used to assist personnel in performing a task. The operator aid reminds staff of information that might otherwise be overlooked and can provide guidance that is not necessarily procedural in nature. Operator aids may come in many forms including system drawings, handwritten notes, information tags, curves, tables, charts, and graphs. Operator aids may be used to address a number of conditions including:

- when additional information is beneficial for operations
- when operational guidance is appropriate for non-repetitive or complex operations
- when operational guidance is needed for sequencing or alignment of operations (e.g., key procedural steps or alignment diagrams) is necessary
- when information regarding the use of operational parameters (e.g., graphs or charts) is necessary.

An operator aid is not the same as a sign or posting, which is a device that is temporarily or permanently affixed or placed in a hazardous area to warn or provide safety instructions to staff that may be exposed to hazards. It is also not a simple reminder (e.g. "turn off heater before you leave") or labeling of reaction vessels or experiments.

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No new requirements shall be initiated by Operator Aids. The group leader maintains an index of Operator Aids. Operator Aids will be reviewed for continued applicability at least once every five (5) years.

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Refer to the SBMS, *Subject Area: Internal Operating Procedures- Developing Operator Aids* ( <http://sbms.ornl.gov/sbmsearch/subjarea/iop/pro3.cfm> ) for additional information on preparing Operator Aids.

Operator Aids require approval only the approval of the Group Leader.

## **6.2 Sketches And Drawings**

**6.2.1** Sketches and formal drawings prepared by M&C personnel should contain, at a minimum:

- the use of recognized industry standards (such as ANSI Y14.5M, *Dimensioning & Tolerancing*) and standardized symbols;
- a traceable identification numbering system
- the name of the individual who prepares or changes a drawing/sketch;
- a method for indicating revisions, including dates of original and subsequent revisions;
- a checking or approval method allowing for any necessary signatures; and
- a filing system.

A sketch or formalized drawing may be needed for many types of activities – for basic needs such as how to prepare a tensile test specimen, up to how a multiple-equipment system with associated safety concerns is put together. The level of care and formality should be commensurate with the purpose or function of the drawing or basic sketch. Drawings describing machining activities should contain enough information to adequately guide either ORNL or off-site machining personnel.

**6.2.2** The responsibility to ensure that the sketch or drawing preparation is consistent with the importance of the intended application is delegated to the person who prepares the drawing and to the Principal Investigator.

- The preparer may be the principal investigator or someone to which the responsibility is delegated. In any case, the preparer should ensure that all technical, safety, quality assurance, and other criteria are addressed during drawing preparation.
- The preparer is also responsible for seeing that drawings are properly approved. In cases involving equipment modifications, updates, or any other type of changes, it is the preparer's responsibility to review and approve changes to the drawings.
- Approval for sketches generally requires no more approval than the signature of the originator.

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- Approval for formal drawings in the M&C Division will typically include:
  - Originator
  - Designer
  - Principal Investigator or Project Manager;
  - QAS;
  - Division Safety Officer and/or Radiation Control Officer if ES&H or specific radiological issues are involved in the design;
  - Other approval signatures as may be defined by specific project quality documents.
- If the original preparer of a sketch or drawing leaves the division, the group leader or program manager should designate an alternate individual to review and approve changes.

**6.2.3** The same criteria of importance used in the preparation of drawings should be used during the process of revision.

- In some cases the drawing should be sent back to the preparing organization for proper revision and related documentation. This should be considered especially in cases where health and safety are involved. It may be sufficient to redline the drawing, explain why the changes were made and sign and date the revision and related explanation.
- In addition, the preparer ensures that each individual is forwarded a copy of the revised drawing to ensure notification of the changes. Copies of the previous version should be collected and disposed of properly. All copies of previous revisions will be marked *OBSOLETE* or destroyed.
- Drawings for each group should be maintained in a central file location or in files held by the primary project engineer for each process, equipment, or other type of operation.
- The Group Leader will maintain an index of current drawings.

## 7. RECORDS

Record copies of instructions, procedures, drawings, and related documents should be maintained for the following periods of time:

- |                      |  |
|----------------------|--|
| • Procedures         | (As long as equipment/process is in service or |
| • Guidelines         | as defined in R&D program documents)           |
| • Experimental plans | (Life of project, then as the program          |
| • Test Plans         | defines)                                       |
| • Checklists         |  |
| • Travelers          | (Life of the item, experiment to which it      |

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- Sketches, Drawings (applies, or as R&D Program defines)
- Procurement Specifications
- Operator Aids

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**APPENDIX A  
LISTING OF POTENTIAL CONTROLLING DOCUMENTATION**

- Project and Program Plans
- QA Plans
- Special Receiving Instructions and Inspection Reports for Material Identification and Control Procedures
- Inspection and Test Plans, Manufacturing Plans, Instrument Calibration Procedures
- Guidelines
- Procedures
- System Design Descriptions
- Engineering Drawings
- Design and Development Planning Reports
- Engineering Study Reports
- Engineering Drawing Lists
- Checklists
- Control Checklists
- Storage, Handling, and Shipping Instructions and Reports
- Procurement Specifications
- Logs
- Maintenance Procedures and Checklists

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**APPENDIX B  
PROCEDURE/GUIDELINE OUTLINE, FORMAT & CONTENT**

The following provides additional information regarding required information, content, and format guidance for procedures/guidelines. Each section must be considered for inclusion in each procedure/guideline.

**I. PROCEDURE/GUIDELINE SECTIONS**

Each section must be considered for inclusion in each procedure/guideline. Depending on the type of procedure/guideline not all sections may be required. Those that will always be required are: Title, Purpose, Scope & Limitations, Environmental, Safety & Health, Responsibilities, Action Steps and Records.

**1. TITLE**

Description of the activity, operation, process, or equipment to which the procedure/guideline applies.

**2. PURPOSE**

Provide a concise statement on why the procedure was developed and what the intent or goal is to accomplish.

**3. SCOPE (& LIMITATIONS)**

Address the applicability and evolutions covered by the procedure. To what equipment, operation, or process does the document apply? Where is the equipment located, or the operation performed (e.g., lab number)? Limitation should only be addressed if situations will arise where exceptions to the procedure/guideline are anticipated.

**4. ENVIRONMENTAL, SAFETY, AND HEALTH (ES&H)**

- Basic precautions that should be taken by anyone using the pertinent equipment or performing the operation or process. If there are no ES&H concerns, enter NONE. Administrative type procedures/guidelines will typically not include this section.
- Reference to the Research Safety Summary (RSS) is included, if applicable.

**5. REQUIREMENTS/REFERENCES**

- Include requirements applicable to the procedure (e.g., RSS, Operational Safety Requirements/Technical Safety Requirements [OSR/TSR] requirements, nuclear

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criticality safety analysis [NCSA], conditions of approval [COAs], safety evaluation report conditions of approvals [SER COAs], etc. shall be included).

- Source Documents - Include a list of documents used in developing the procedure, and which may be maintained in the PHF (Procedure History File), unless readily accessible elsewhere.
- Performance Documents - Include a list of documents needed by the user to complete the procedure.
- Other sections to be considered include: Calibration, Applicable Standards (ASTM, others).

## **6. RESPONSIBILITIES**

From whom is permission needed before operation of the equipment? Who are the qualified personnel? What does a perspective operator have to do to be qualified?

## **7. PROCEDURE/GUIDELINE ACTION STEPS**

Action steps shall be written to identify what activity is to be performed, by whom, involving which structures, systems, and components, and in which order of performance completion to achieve the procedure objective.

## **8. RECORDS**

Include a list of records generated by the procedure, including completed forms, approval and concurrence sheets, etc. The data sheets, logs, analytical results, training record(s), or other paper or electronic as well as material archive samples that should be kept at the end of the described process or activity.

## **9. APPENDICES**

Include information such as definitions, acronyms, graphs, flow sheets, forms, approval and concurrence sheets, and other supplemental information. Information in appendices is not constrained to using the formatting suggested for the text portion of a procedure.

## **II. CONTENT CONSIDERATIONS**

- Instructional documents must include safety considerations in the appropriate section of the procedure/guideline. If an operation has the potential to be unsafe and there are methods available to reduce or eliminate dangers inherent in the operation, the preparer has the responsibility to spell them out in the body of the procedure/guideline. All procedures and guidelines will be reviewed by the DSO/RCO to ensure that adequate precautions or concerns are defined and mitigated. If there are no considerations of this type, the preparer should enter NONE in this section of the document. Personnel training

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and qualification requirements should also be addressed in the Responsibilities section of the procedure/ guideline

- Other types of content may include calibration methods, records to be kept after operation (strip charts, log sheets, etc.), maintenance measures, reliability indicators, or other considerations needed to ensure that an equipment operation or an experimental process is performed safely and successfully.
- Sections Which Must Be Considered For Inclusion - In general, procedures/guidelines should contain clearly identified sections including: purpose; scope; environmental, safety, and health concerns; procedure or guideline (steps to perform activity), references, calibrations, records, and other applicable documents, applicable ASTM or other standards and any appendices that may be needed. Other sections may be included.

**III. PROCEDURE/GUIDELINE FORMATTING**

- The following is an example of action step levels for formatting:

|  |
|--|
| <p><b>5. FIRST LEVEL HEADING</b> [All caps &amp; Bolded]</p> <p><b>5.1 <u>Second Level Heading</u></b> [Initial caps, Underlined, &amp; Bolded]</p> <p><b>5.1.1 Third Level Heading</b> [Initial caps &amp; Bolded]</p> <p><b>5.1.1.1</b> Action steps following a third level heading or</p> <p style="padding-left: 40px;">1. Action steps following a third level heading</p> |
|--|

- The following table describes the numbering system for procedures/guidelines.

| Procedure/Guideline Numbering System  |  |  |                   |
|---|--|--|-------------------|
| <b>MET</b>  | <b>CER</b>   | <b>SOP</b>   | <b>52</b>         |
| Identifies division originating document.<br>MET = Metals & Ceramics Division | Identifies group within division originating document.<br>CER = Ceramic Processing Group | Identifies the type of document.<br>SOP = standard operating procedure<br>SOG = guideline<br>OA = operator aid | Sequential number |

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**APPENDIX C  
SUGGESTIONS FOR PREPARING SPECIFICATIONS, CHECKLISTS, TRAVELERS**

**I. PROCUREMENT SPECIFICATIONS**

Additional instructions for preparing purchase specifications are available from a number of sources including the M&C Procurement Office, the M&C Quality Assurance Office, and via the SBMS. The following is a suggested listing of content to include in a purchase specification.

- **Scope** – identify the scope of the specification. What is the end product or service that is desired? Are there limitations, will the specified item or service be utilized with specific models, serial numbered units, etc.?
- **General Description** – describe in appropriate detail the end product that is desired. In many cases drawings may need to be included to specifically define the product.
- **Environmental, Health, and Safety, and Quality Assurance Considerations** – specific environmental, safety, health, and quality assurance concerns or requirements need to be identified (e.g., operating in an explosive atmosphere, corrosive atmosphere, extremely tight tolerances, breaking sharp edges, pinch points, insult to the environment, compliance to specific permits, etc.)
- **Detailed Requirements**, as applicable, consider such things as:
  - System Requirements- current or power requirements (electrical), capacities, weight, dimensional, material, etc.
  - Environment – special operating conditions (explosive, corrosive, etc.), specific environmental permits/requirements, potential for environmental insult, etc.
  - Software and Interfaces – are there other systems with which this product will have to interface (electrically, dimensionally, mechanically, etc.)? Is special software required for operation or will the product have to interface with software from another operating system?
  - Data Acquisition Systems – are specific data acquisition systems/methods required? Special software? External data acquisition systems requiring interfacing? Specific types of data to be obtained or monitored?
- **Identification and Acceptance Testing** – Identify how the product is to be identified (model numbers, serial numbers, types of labels, location of identification plates, size of lettering, color of lettering/labeling, etc. Define the acceptance testing that will be required to be met for acceptance of product. Specific industry standards may be specified (ASTM, etc.), specific testing documents generated and supplied, etc.
- **Documentation** – define what documentation will be required to accompany the product (material certifications; inspection documents; testing documents; operating, repair, installation manuals, etc.). If maintenance of inspection/testing documentation, by supplier, is required what is to be maintained, how long, etc. May even define specific document format and content.

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**NOTE:** Good examples of previously-prepared specifications can be obtained from the Division's Procurement Office and the QA Office. Help can also be obtained from staff who have purchased similar equipment or other items.

## **II. CHECKLISTS**

The format of the checklist will typically depend on the information to be monitored by use of the checklist. Suggested components for the checklist are:

- **Title** – identifying topic/item/procedure/process for which checklist is being developed
- **References** – include documents from which requirements included in checklist have been drawn (optional, but recommended)
- **Date** – date that checklist is being filled out/completed
- **Name** – name of person using the checklist to monitor procedure, process, etc.
- **Organization** – may be name of organization developing and utilizing the checklist or of the organization/activity being monitored

Table format is often useful for checklists but not required. Use the format that best suits the data to be obtained or activity to be monitored. It may be useful to include a date or indicator on checklist to identify versions of checklist if subsequent versions may exist.

## **III. TRAVELERS**

Travelers are documents which physically track an item, document, etc., through a process to provide traceability, progress determination, control, or other requirements. Like the checklist, the format can be dependent on the item, environment, and purpose. The traveler may be a datasheet or tag attached to an item as it progresses through a process. Suggested content for the traveler includes:

- **Description** – name, description, etc. of item
- **Identifying Number** – lot numbers, process numbers, serial numbers, etc. A unique identifying number for the item which differentiates it from other items in process.
- **Step Check-offs** (optional) - may include step check-offs to identify progress through a process
- **Responsible Individuals** – if problems arise, who to contact; or upon completion of a step or a process, who should be contacted.
- **Pertinent or Required Information** – possibly inspection data, or instructions for the next step in the process.
- **Completion Instructions** – once item has completed the process, what is the disposition of the item, traveler, etc.

There are no specific requirements or format for a traveler. Include the pertinent data but no more than is needed to perform the function for which intended.