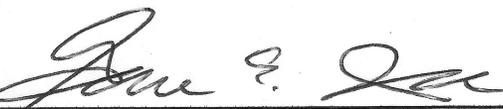


Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

Approved:  5/15/12
M. C. Vance
Quality Representative
Date

Approved:  5/16/12
T. W. Strader
Group Leader, Research Support
Date

Approved:  5/17/12
G. E. Ice
Division Director
Date

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

TABLE OF CONTENTS

1. PURPOSE	3
2. SCOPE	3
3. REQUIREMENTS	3
4. ADDITIONAL REFERENCE	3
5. RESPONSIBILITIES	3
5.1 <u>Group Leaders</u>	3
5.2 <u>MSTD Research Support Group</u>	4
5.3 <u>Staff Members</u>	4
5.4 <u>Project/Program Manager</u>	4
6. INSTRUCTIONS, PROCEDURES, DRAWINGS, AND RELATED DOCUMENTS.....	4
6.1 <u>Procedures, Guidelines, Specifications, Checklists, And Other Documents</u>	4
6.1.1 Technical Data, Technical Notebooks.....	4
6.1.2 Procedures & Guidelines.....	4
6.1.3 Experimental plans, test plans, checklists, travelers, and other documents	8
6.1.4 Procurement specifications	8
6.1.5 Operator Aids	8
6.2 <u>Sketches & Drawings</u>	9
7. RECORDS	10
APPENDIX A, LISTING OF POTENTIAL CONTROLLING DOCUMENTATION.....	11
APPENDIX B, PROCEDURE /GUIDELINE OUTLINE, FORMAT & CONTENT.....	12
APPENDIX C, SUGGESTIONS FOR PREPARING PROCUREMENT SPECIFICATIONS, CHECKLISTS, TRAVELERS.....	15

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

1. PURPOSE

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

2. SCOPE

This administrative procedure applies to the control of documentation for experimental, developmental, or production activities within the Materials Science and Technology Division (MSTD). Additional mandates may be imposed through project or program quality assurance plans developed to address unique sponsor needs or requirements. Administrative procedures and related division-level documents shall be developed in accordance with the applicable portions of this procedure.

3. REQUIREMENTS

ORNL Standards-Based Management System (SBMS), *Subject Area: [Internal Operating Procedures](#)*

4. ADDITIONAL REFERENCE

[ORNL Quality Assurance Program Description](#)

5. RESPONSIBILITIES

5.1 Group Leader – Ensures that all activities, associated hazards, and mitigating actions are covered under a current Research Safety Summary (RSS), and 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.

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

- Environmental, safety, health, and quality factors associated with group laboratory activities and described in the applicable RSS.
- Explicit requirements (if any) of a project or program sponsor funding group work and conveyed through a program manager or principal investigator.
- Group leader's judgment concerning the need for formal documentation.

Each group leader has the responsibility for ensuring necessary documents are available in the work area where they are needed. It is also his/her responsibility to ensure that documentation is kept current.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

5. 2 **MSTD Research Support Group** – Provides expertise and assists management and staff in determining when work controlling documents are needed and ensuring that documentation meets division and/or sponsor requirements.
5. 3 **Staff Member** - Ensures work meets the requirements identified in work controlling documents such as guidelines, procedures, and drawings.
5. 4 **Project/Program Manager or Principal Investigator** – Ensures that management and staff are informed of any specific sponsor requirements associated with work controlling documents.

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 or deemed necessary by each group leader, principal investigator, or program manager in controlling work is included in Appendix A, *Listing of Potential Work Controlling Documents*. Control of the procedures, guidelines, specifications, checklists, and other documents is described below.

6.1.1 **Technical Data, Technical Notebooks**

It is expected that most technical data will be digitally stored. Staff members need to ensure that a level of technical data necessary to substantiate how research was performed and results analyzed is maintained as records. Technical notebooks are the baseline paper-based method for records maintenance. General use of technical notebooks and the data contained therein is covered in the ORNL Standards-Based Management System (SBMS), in Records Management ([Instructions for Use of This Research and Technical Notebook](#)), in the subject area entitled *Records*. This document provides instructions and guidelines for notebook content and related requirements.

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 the planned use.
 - A work controlling document will only be identified and labeled a *procedure* if it is intended to be strictly followed with no deviation from the steps or the order or sequence of the steps described. Certain types of activities may require procedures because of the risks associated with their conduct.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

- 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.

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

- Address the complexity of or hazards/risks associated with an operation. Specific instructions are needed to ensure environmental, safety, or health issues or hazards described in the pertinent RSS are addressed. This is especially important if equipment is to be operated outside of the stated design intent as described in manufacturer's manuals and related instructions. This is especially important when interlocks or other hazard mitigation devices are bypassed. Instances where a device will be bypassed must be reviewed as a new hazard through the RSS process as well.
- Ensure the desired outcome for important activities.
- Ensure the reproducibility and repeatability of results.
- Consolidate pertinent operational information dispersed throughout a manual, or in laboratory notebook entries, or other sources, or to capture a body of expertise possessed by an individual or team.
- Provide a consistent method for mentoring/training new operators concerning a piece of equipment or a particular operation.
- Further describe operating restrictions identified in the applicable RSS.
- Provide guidance for successful emergency situations, when signage is not enough (e.g., emergency shutdown steps necessary to place equipment in safe status).

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.

The scope of a procedure/guideline may cover an individual piece of equipment or may cover a process covering the use of several pieces of equipment.

The use of formal written documentation should be based on need. If current available methods provide the necessary control of a given activity, no document need be considered. Group leaders should make these decisions based on any ES&H or quality issues associated with each activity and the planned use of the information/data resulting from the activity. Members of the Research Support Group can provide guidance when questions arise concerning whether or not work controlling documents are needed.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

6.1.2.2 Format

Appendix B, *Procedure/Guideline Outline, Format & Content*, provides typical 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 based on project or program needs)
- Group Leader
- Division Safety Officer (DSO), (except administrative procedures)
- Radiation Control Officer (RCO), (if procedure/guideline involves radiation)
- Division Quality Representative (QR)

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. Groups or project teams may also consider the use of the ORNL Integrated Document Management System to control their work controlling documents. This method provides a low-cost and easy option for staff access to current documents.

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 files (electronic storage is adequate) and the other on the equipment or in the area where the procedure is used. It is each staff member's responsibility to ensure that any document used is first verified as current prior to use.

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 including those that result from using equipment in ways other than those described in the operating manual, 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

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

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 last approval 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:

These changes are not for non-intent or editorial changes. Since these types of changes have no impact on the work, they are only required to be addressed in the next scheduled revision.

When redline changes are made, additional text shall be legible and written on the same page(s) to which the change applies. Removed text shall be crossed out using a single line. All changes shall be initialed and dated, with the principal investigator's and program manager's or group leader's initials. Any redline change that alters or introduces a new hazard into the described activities must also be reviewed by the DSO as a part of the RSS process as the review may prompt a change to the RSS.

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 shall be incorporated into a revision to the permanent procedure/guideline within six (6) months of redline approval.

4. Mentoring

In some instances it may be very difficult to write a procedure or guideline for a piece of equipment, an operation, or a process. The operation may be highly complex and dependent upon 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, may suffice to ensure safe, effective equipment/ process operation. Any associated hazards must be vetted through the RSS process to ensure consistent effective mitigation.

To counter the lack of established instructional documentation where they may be perceived as needed, formal documentation should be prepared outlining the qualifications of the individual(s). Access to the equipment or operation can be restricted to only the qualified individuals. This type of qualification may also be necessary based on specific project or program sponsor needs.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

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., calibration, maintenance, reliability, mentoring/training), necessary to ensure the success of an operation or activity and the validity of the results. They shall also be reviewed, approved, and distributed according to the requirements of the program or project for which they are written. The program or project manager should decide who should review these documents based on content and sponsor needs. Appendix C, *Suggestions for Preparing Specifications, Checklists, Travelers*, provides guidance concerning these types of documents.

6.1.4 Procurement Specifications

Procurement specifications list any and all of the attributes that the procured items or services should possess to do the job for which they are intended. Any warranties, manuals, inspections, tests, service requirements, certifications, acceptance inspection/ tests, vendor training, maintenance, or other considerations are spelled out in the specification. Appendix C also provides guidance on procurement specification preparation.

The minimum required reviewers for procurement specifications are:

- Author
- Project Engineer or Principal Investigator
- QR

Examples of previously-written procurement specifications can be obtained from the MSTD QR. The QR 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](#)*.

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.
- Operational guidance is appropriate for non-repetitive or complex operations.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

- Operational guidance is needed for sequencing or alignment of operations (e.g., key procedural steps or alignment diagrams) is necessary.
- Information regarding the use of operational parameters (e.g., graphs or charts) is necessary.

No new requirements shall be described in an operator aids. If more formality is needed, a procedure or guideline should be considered for use.

Refer to the SBMS subject area *Internal Operating Procedures - [Developing Operator Aids](#)* for additional information on preparing these types of documents. Operator aids are required only to be dated and approved by the Group Leader or his/her designee..

6.2 Sketches and Drawings

6.2.1 Sketches and formal drawings prepared by or for MSTD 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 prepared or revised 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.

A sketch or formalized drawing may be needed for many types of activities – for basic needs such as how to machine a 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 in successfully completing the job.

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 (PI).

- The preparer may be the PI 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 and included 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.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

- Approval for sketches generally requires no more approval than the signature of the originator.
- Approval for formal drawings in the MSTD Division will typically include:
 - Originator
 - Designer
 - Principal Investigator or Project Manager;
 - QR
 - Division Safety Officer (DSO) and/or Radiation Control Officer (RCO) if ES&H or specific radiological issues are involved in the design;
 - Other approval signatures as may be mandated 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 future changes.

6.2.3 The same level of care and formality 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 should be maintained in a central file location or in files held by the PI or other personnel associated with each project, program, process, or equipment to which the drawing applies.

7. RECORDS

Record copies of instructions, procedures, drawings, and related documents should be maintained for 10 years after they are no longer used or longer if mandated by an R&D sponsor. Many division projects and programs are also required to meet more stringent sponsor requirements for records associated with work controlling documents specific to their work and these should be conveyed to technical staff through the project/program manager or PI.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

**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

*Research Safety Summaries are controlled through the [Research Hazard Analysis and Control System](#)

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

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

The following provides additional information regarding content and format guidance for procedures/guidelines.

I. PROCEDURE/GUIDELINE SECTIONS

Each section listed below should be considered for inclusion in each procedure/guideline. Depending on the type of procedure/guideline not all sections may be applicable or required. Those that will always be required are: Title, Purpose, Scope & Limitations, Environmental, Safety & Health, Responsibilities, Procedure/Guideline 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 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.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

- 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 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, training forms, and other supplemental information.

II. CONTENT CONSIDERATIONS

- Work controlling documents must include safety considerations in the appropriate section of the procedure/guideline. The RSS process – including the activity-based hazard analysis - should also address these considerations as a part of the work review process. 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 as an amplification of the hazards and mitigating activities described in the applicable RSS. All procedures and guidelines will be reviewed by the DSO 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 and qualification requirements should also be addressed in the Responsibilities section of the procedure/ guideline
- Other types of content may include calibration methods, test criteria, maintenance measures, reliability indicators, use of standardized test methods (e.g. ASTM) or other considerations needed to ensure that an equipment operation or an experimental process is performed safely and successfully.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

III. PROCEDURE/GUIDELINE FORMATTING

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

<p>5. FIRST LEVEL HEADING [All caps & Bolded]</p> <p>5.1 <u>Second Level Heading</u> [Initial caps, Underlined, & Bolded]</p> <p>5.1.1 Third Level Heading [Initial caps & Bolded]</p> <p>5.1.1.1 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 MSTD procedures/guidelines.

Procedure/Guideline Numbering System			
*MET	**MPM	SOP	***52
Identifies division originating document. MET = Historical 3-letter MSTD document designation	Identifies group within division originating document. MPM = Materials Processing and Manufacturing Group	Identifies the type of document. SOP = standard operating procedure SOG = guideline	Sequential number

* The MET designation (for the previous Metals & Ceramics Division) will be retained for document numbering continuity.

** Group names have frequently changed, but numbering systems based on previous group names can be maintained for continuity and ease.

*** Sequential numbering of documents is primarily to ensure that each document has a unique number and that no number is used on more than one document.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

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 MSTD personnel who enter requisitions and orders into the ORNL procurement system, the MSTD Quality Representative, 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.

Control and Content of Instructions, Procedures, Drawings, and Other Work Controlling Documents in the Materials Science and Technology Division

NOTE: Good examples of previously-prepared specifications can be obtained from the Division's Procurement Office and the QR. 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.