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Standard Operating Procedures

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Standard Operating Procedures

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- A standard operating procedure or SOP is a set of instructions that address the who, what, where, when and how of an activity.

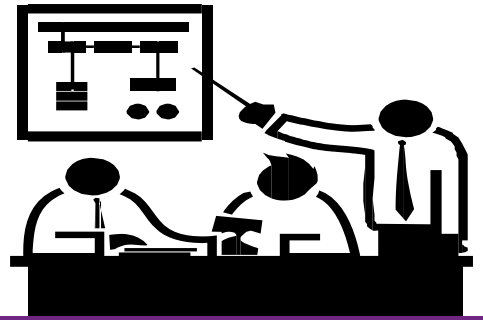
- They may also address the why

- They are meant to be a guide to standardize the activity, to aide in producing reliable data

Standard Operating Procedures

- SOPs detail regularly recurring work to help ensure the process is completed correctly, that variability is minimized and promote quality

- A facility may have a variety of staff performing tasks over different shifts or weekday/weekend. SOPs provide assurance that the work is completed consistently.



Standard Operating Procedures

- When to write an SOP:
- Common topics include:
  - Animal care such as cleaning cages, housing densities, animal observations
  - Common procedures such as animal identification, routine blood or tissue collection
  - Common lab assays
  - Data collection, storage
  - Equipment use, maintenance and calibration

- **Depending on the type of facility, regulations may dictate when and what needs to be captured within SOP

Standard Operating Procedures

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- SOPs are vital to ensure processes are completed in the same way over time and should be:
  - Clear and Concise
  - Complete
  - Consistent
  - Controlled
  - Current

Clear and Concise

- SOPs should be written in plain language.
- Any highly technical jargon should be avoided or clearly defined
- Steps should be explained thoroughly, but concisely.

Clear and Concise

- Avoid long sentences or paragraphs explaining tasks
- Write steps in short, descriptive sentences
- Use pictures or diagrams to help visually illustrate
- Do not use vague wording, for example:
  - After calibrating the thermometer it should be labeled with the next calibration date
  - After calibrating the thermometer, it must be labeled with the next calibration date

Clear and Concise

- SOPs should not take the place of training, but are a great training tool.
- They should be written such that a person with some familiarity with the area and procedure could successfully complete the procedure
- Consider a checklist or consolidated set of work instructions for complex procedures for staff to reference during work

Complete

- Ensure all steps are accounted for within the process
- Write procedure in chronological order with clear beginning and end points
- Include common troubleshooting where applicable and when and who to notify

Complete

- It can be helpful to reference other SOPs or materials as opposed to re-stating sections
  - Equipment manuals
  - Material Safety Data Sheets
  - Personal Protective Requirements

Complete

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- Look to combine or consolidate existing SOPs for similar procedures by adding a section when appropriate

- For example, an SOP titled Procedure for Lab Rodent Identification could contain sections for several different ID methods as well as direction for when to use each as opposed to a separate SOP for each method

Consistent

- Format, font, tone should be the same from SOP to SOP

- Layout and flow should be the same
  - Each SOP should contain the same sections in the same order:
    - Purpose
    - References
    - Materials
    - Procedure
    - Forms and documentation

Format Example

- 1.0 QUALITY ASSURANCE

- 2.0 DESCRIPTION AND REFERENCES
  - Description
    - The purpose of this standard operating procedure is to detail the steps required to reprocess an IBS Park Bioservices isolator. Reprocessing involves the removal of animals and supplies as well as the cleaning and sterilization of the dirty isolator.
  - References
    - 2.2.1 Document SE1202 – Personal Protective Equipment Requirements
    - 2.2.2 Document SE1207 – Preparation of Approved Sterilants/Disinfectants

Consistent

- Level of detail should be similar
- Sections not needed for a SOP can have N/A
- Consider limit to the number of step per page, pages per procedure

Controlled

- A person or small group should maintain ownership
- Revisions should be routed through owners and approved by relevant parties (Vet, IACUC, etc.)
- Steps should be taken to ensure old versions are removed from all areas and that only the most recent version is available

Controlled

- SOPs should be numbered and titled consistently
- Each SOP should have a unique identifier
  - EX. Dept XYZ-001
- Should be readily available in the work space, consider electronic systems
- Should have the approved and expiration dates on the document

Current

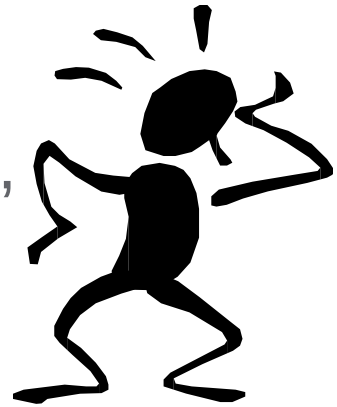
- SOPs should be re-visited on a regular basis
  - Review for current best practice
    - Has there been drift in the procedure
    - Are there non value added activities or documentation
  - Review for regulatory changes
    - Are all steps in compliance

Current

- Ensure equipment and materials are still accurate
  - Are specific brands referenced and if so, are they necessary
- Is the listed Owner the most appropriate
- Are other groups using the document

Deviations

- Deviations from SOP should be avoided, but can happen
- Need system to report, document and investigate
- When writing SOPs, try to envision areas where deviation may occur and address within the document
- Deviation can lead to revision of procedure, time or cost savings, new ways of doing things



Suggested Topics for SOPs

- Procedure For Microbiological Monitoring In Isolators
- Packing and Receiving Procedures For Germ Free Shippers
- Gnotobiotic Technique For Hooking Up Cylinders and Entering and Exiting Supplies
- Gnotobiotic Husbandry For Isolators
- Procedure For Building an Isolator
- Isolator Contamination Prevention
- Personal Protective Equipment Requirements

Suggested Topics for SOPs

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- Raw Materials Flow - Distribution/Release of Raw Materials Entering IBS Productions Areas
- Documentation of Significant Events for Semi-Rigid Isolators
- Raw Materials Flow - Distribution/Release of Raw Materials Entering IBS Productions Areas
- Raw Materials Quality Assurance System
- Preparation and Use of Approved Sterilants/Disinfectants
- Colony Health Monitoring - Maintenance and Selection of Sentinel Animals
- Identification and Evaluation of Pain and Distress in Laboratory Rodents

References

- The Germ Free Animal in Biomedical Research
  - Edited by Marie E. Coates and Bengt E. Gustafsson
- Isolation Technology: A Practical Guide
  - By Tim Coles
- 50 Years of Laboratory Animal Science
  - AALAS Publication