

Handling Regulatory Agency Inspections	SOP #:	##-###
	Effective:	MM/DD/YYYY
	Cancels:	New

1. PURPOSE

To provide a consistent approach to hosting and managing regulatory health agency and notified body inspections.

2. PERSONNEL AFFECTED

All personnel in the Quality Unit (e.g., Quality Assurance, etc.), Regulatory Affairs, and Corporate Compliance departments, as well as current members of the Site Inspection Response Team.

3. SPECIFIC RESPONSIBILITIES

QUALITY, REGULATORY AND COMPLIANCE MANAGERS

Responsible for:

- Ensuring implementation of this procedure with their teams at various sites, including members of the Site Inspection Response Team
- Directing internal departmental activities related to regulatory agency inspections
- Being available during an inspection to explain, interpret, and/or clarify answers as appropriate
- Helping the company to manage and respond appropriately to any inspection findings.

INSPECTION HOST

An ad hoc member of the Site Inspection Response Team, and often the Quality Manager by default, responsible for:

- Coordinating the inspection and its logistics
- Acting as the primary contact for any regulatory health agency and notified body inspectors
- Facilitating interactions and schedules between inspectors and company personnel
- Leading the internal company preparations and response to any inspection findings

- Coordinating with relevant site functional management any special requests during the inspection.

Whenever possible, the Inspection Host is to be selected by the Site Inspection Response Team or the Senior Management Representative immediately following the initial notification and scheduling of the inspection by the regulatory health agency or notified body.

SITE INSPECTION RESPONSE TEAM (SIRT)

Comprised of departmental managers, senior subject matter experts (SMEs), and at least one member of the site's senior management, all of whom are able to:

- Coordinate and direct their respective department's inspection activities and resource allocation
- Answer inspection questions accurately, completely, and efficiently
- Be available during an inspection to explain, interpret, and/or clarify answers as appropriate
- Support and take accountability for their respective department's responses to any inspection findings
- Help the company to manage and respond appropriately to any inspection findings.

At minimum, the Site Inspection Response Team should be comprised of a primary and a backup member from:

- Quality Unit
- Regulatory Affairs
- Information Technology (IT)
- Records and Information Management (RIM)
- Senior management team.

Additional functional members (such as from Engineering, Manufacturing, Purchasing, Validation, Clinical, Internal Audit, etc.) should be appointed based on the scope of the regulatory agency inspection, and may be dependent on how an inspection unfolds.

4. PROCEDURE

<u>Action By:</u>	<u>Step:</u>	<u>Action:</u>
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Greeter (security, receptionist, etc.)	1	Greets the inspectors upon their arrival at the facility and notifies the site Quality Manager (or his/her backup as necessary).
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| Quality Manager | 2 | Notifies members of the Site Inspection Response Team (SIRT) of the arrival of the inspectors, and requests logistical support to the pre-selected meeting room that will be used as the “audit room” for the duration of the inspection. <ul style="list-style-type: none">• Appropriate refreshments should be made available• SIRT members should make their way to the audit room to meet the inspectors. |
| Quality Manager | 3 | Welcomes the inspectors to the facility, verifies their credentials, inspection authority, and then escorts the inspectors to the audit room. <ul style="list-style-type: none">• Consider bringing the current Site Inspection Proof Binder if not already available in the audit room or sent to the inspectors ahead of time. |
| Quality Manager | 4 | Introduces the members of the Site Inspection Response Team and identifies the designated Inspection Host. <ul style="list-style-type: none">• At this juncture, the Inspection Host is the inspection handling and response lead. |
| Inspection Host | 5 | Identifies the note-taker(s) or scribe(s) that will escort the inspectors and take notes during the inspection. |
| Inspection Host | 6 | Leads the company portion of the inspection opening meeting. <ul style="list-style-type: none">• Typically this will include a short presentation covering the overview of the facility, its regulated activities (relevant to the specific regulatory health agency or notified body), and any products developed, made, stored or distributed from the site.• This should also include clarifying the scope of the inspection, the anticipated duration and schedule, any initial records requested, and coordinating any initial personnel interviews. |
| Inspection Host | 7 | Conducts any requested site tour along with any members of the Site Inspection Response Team who are SMEs in particular areas of interest to the inspectors (dependent on inspection scope). <ul style="list-style-type: none">• Make sure to point out and clarify to the inspectors any physical controls on various areas (such as secured areas, clean rooms, physical barriers, etc.). |
| Quality Manager | 8 | Notifies the remainder of the site’s senior management team of the inspection, its scope, and current expectations. <ul style="list-style-type: none">• This should occur immediately following the opening meeting• Provide a draft company-wide inspection notification memo for the senior management representative on the SIRT to issue. |

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| SIRT senior management member | 9 | <p>Issues an inspection notification memo to all site employees; the memo should cover:</p> <ul style="list-style-type: none">• Scope of the inspection• Expected inspection schedule and estimated duration• Reminder of SIRT members and encouragement to direct any questions to such individuals• Reminder link to this SOP• Reminder link to the company ethics policy. |
| Inspection Host | 10 | <p>Coordinates the inspection as it progresses and tracks the items requested by the inspectors versus the items actually provided, noting intent of the request, date requested and date provided.</p> <ul style="list-style-type: none">• Copies of any documents given to the inspector should be marked as per the SOP on controlled documents; for paper documents, use, if possible, colored paper (such as light blue, pale yellow, etc.).• Electronic copies of any records should be provided on CD or USB as requested by the inspectors, identified as copies, virus-scanned, and secured (inasmuch as possible) as read-only. |
| Inspection Host | 11 | <p>Hosts a daily debrief session with the inspectors and the members of the Site Inspection Response Team.</p> <ul style="list-style-type: none">• Obtain clarity from the inspectors on any preliminary observations and concerns, schedule interviews for the next day, and provide any immediate, completed fixes (along with relevant supporting evidence). |
| Inspection Host | 12 | <p>Schedules and leads a private daily debrief session with just the members of the Site Inspection Response Team.</p> <ul style="list-style-type: none">• Use this meeting to track current issues, delegate investigation and fixes to members of the Site Inspection Response Team, and apprise senior management of the inspection progress. |
| Inspection Host | 13 | <p>Prepares for the inspection closeout meeting along with members of the Site Inspection Response Team and relevant functional area managers and SMEs.</p> <ul style="list-style-type: none">• Identify all issues resolved during the inspection along with relevant supporting documentation.• Determine any questions that need to be answered during the closeout to help with any inspection response and further corrective and preventative actions. |

- Inspection Host 14 **Leads** the company portion of the inspection closeout meeting, making sure to obtain clarifications needed and present any evidence of issue resolutions (if available).
- Verify the response time permitted to the company and to whom any response should be sent
 - Have a member of the Site Inspection Response Team escort the inspectors off the premises to ensure the inspection has closed.
 - At this point, the response clock is ticking.
- Inspection Host 15 **Schedules** a post-inspection review and response meeting as soon as possible to cover:
- Current status of open and closed issues
 - Assignments to rapidly determine remediation plans
 - Proposed preventative actions and effectiveness steps
 - Identify remaining next steps
 - Schedule the next response meeting.
- Inspection Host 16 **Assembles and files** the Inspection File (see “Records Output” below) with help from members of the Site Inspection Response Team and the any note-taker(s)/scribe(s).
- If retained electronically on the company network, courtesy links to the Inspection File may be sent to any of the company individuals involved in the inspection.

5. ASSOCIATED FORMS AND TEMPLATES

There are no official company forms associated with this SOP.

6. RECORDS OUTPUT

Completion of this process generates one official company record set:

- Inspection File.

The Inspection File is the set of internally generated items during the inspection such as any notes taken, duplicate photographs taken, the initial overview provided in the opening meeting, the log of items requested versus provided, the list of issues resolved during the inspection versus remaining open after the closeout meeting, and so forth. Any initial scheduling record from the regulatory health agency or notified body should be included in the Inspection File along with any document provided to the

company during the inspection closeout. Eventually, the file should be updated with a copy of the company's written inspection response (if any).

The Inspection File is to be retained by the site Quality Manager as part of the overall quality and compliance records.

The Inspection File is to be retained as per [insert your company name] Records Retention Policy and record retention schedule or, in lieu of such a policy, for four years after the record is superseded.

7. REFERENCES

Regulations:

- various (depends on the specific regulatory health agency or notified body involved)

Guidance Documents:

- FDA Inspection Operations Manual (2007)
- ISO 19011 Guidelines for Auditing Management Systems (2011)
- GHTF/IMDRF SG4-N28R4 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers, parts 1-5 (2008)

Related Policies and SOPs:

- POL ##-## Ethical Behavior and Personal Responsibility
- POL ##-## Site Visitor and Guest Access
- SOP ##-### Controlling and Securing Controlled Records
- SOP ##-### Creating and Maintaining a Site Inspection Proof Binder
- SOP ##-### Responding to Regulatory Agency Inspection Findings
- SOP ##-### Tracking Regulatory Agency Communications and Commitments

8. APPROVALS

APPROVER NAME	TITLE	DATE	SIGNATURE

9. REVISION HISTORY

NUMBER	REVISION DETAILS	EFFECTIVE DATE
DRAFT	New draft	--
01	Original issue	

For more practical inspection advice and training, articles, sample SOPs, case studies and SmarterCompliance™ Toolkit checklists and templates, visit the Cerulean website:

www.ceruleanllc.com

Further inspection-related SmarterCompliance™ tools to consider:

- Site Inspection Proof Binder Checklist
- Pre-Inspection Preparation Checklist
- Inspection Observation-Closure Matrix
- Inspection Handling Checklist
- Post-Inspection Response Checklist

For expert inspection and compliance remediation help, contact Cerulean today

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