Virtual Audits: Planning is Key

30 July 2020

NAEM Webinar Presented by convergence consulting LLC

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Speaker Introductions

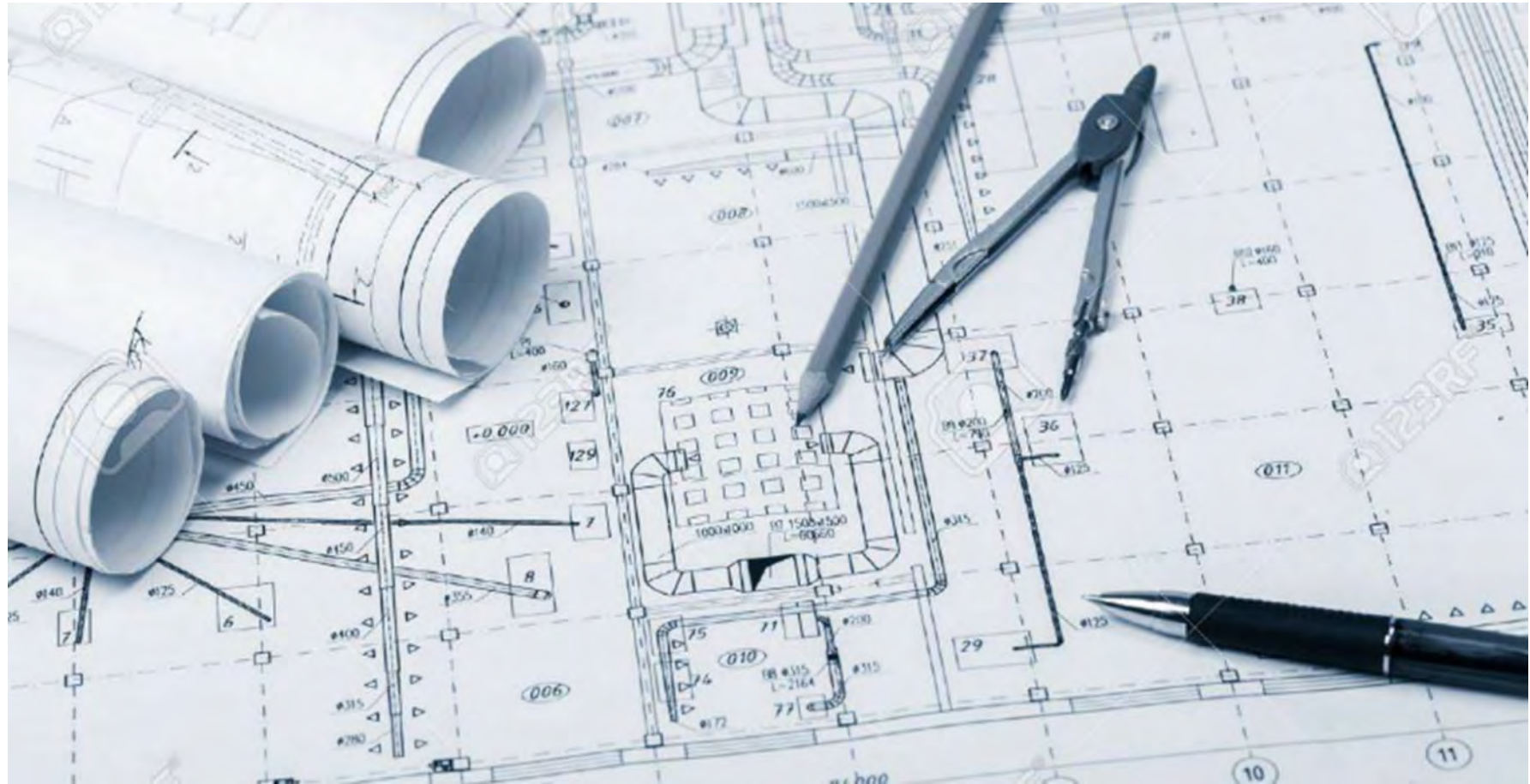Leigh Leonard
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Takeda Pharmaceutical Co. Ltd.
Head Corporate EHS Audit

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Takeda Pharmaceutical Co. Ltd.
Corporate EHS Audit Lead

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Virtual Audits: Planning is Key

INTRODUCTION

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Virtual Audits: Planning is Key

Virtual Audits: Planning is Key

Webinar Purpose and Objectives

To enable EHS audit managers to initiate an agile planning process driven by continuous improvement to achieve better performance.

- ✓ Make a strong case for virtual audit program planning
- ✓ Explain six concrete steps to plan a virtual audit program
- ✓ Explore how to plan and execute at the same time

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What is a Virtual Audit?

- Working definition: A virtual audit…
  - Is conducted when, for various compelling reasons, the ability to undertake physical inspections and observations is restricted, but the duty to audit is still applicable.
  - Can and should be conducted in a manner that is substantially consistent with IIA/BEAC, ASTM, and other recognized EHS auditing standards.
  - Goes beyond the remote "desktop" audit by including one or more technology enhancements to make the audit more authentic.

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Why Plan?

What is Planning?

- Different than "pre-audit"
- Looking at virtual audits as a new or different audit program
- Making high level decisions and creating/updating procedures accordingly

Some Program-level Questions:

- How do staff roles, qualifications, and expertise differ from site visit audits?
- What approaches and technology are available and will be permitted?
- How will results be reported?

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Why Plan?

There is pressure to conduct virtual audits quickly but...

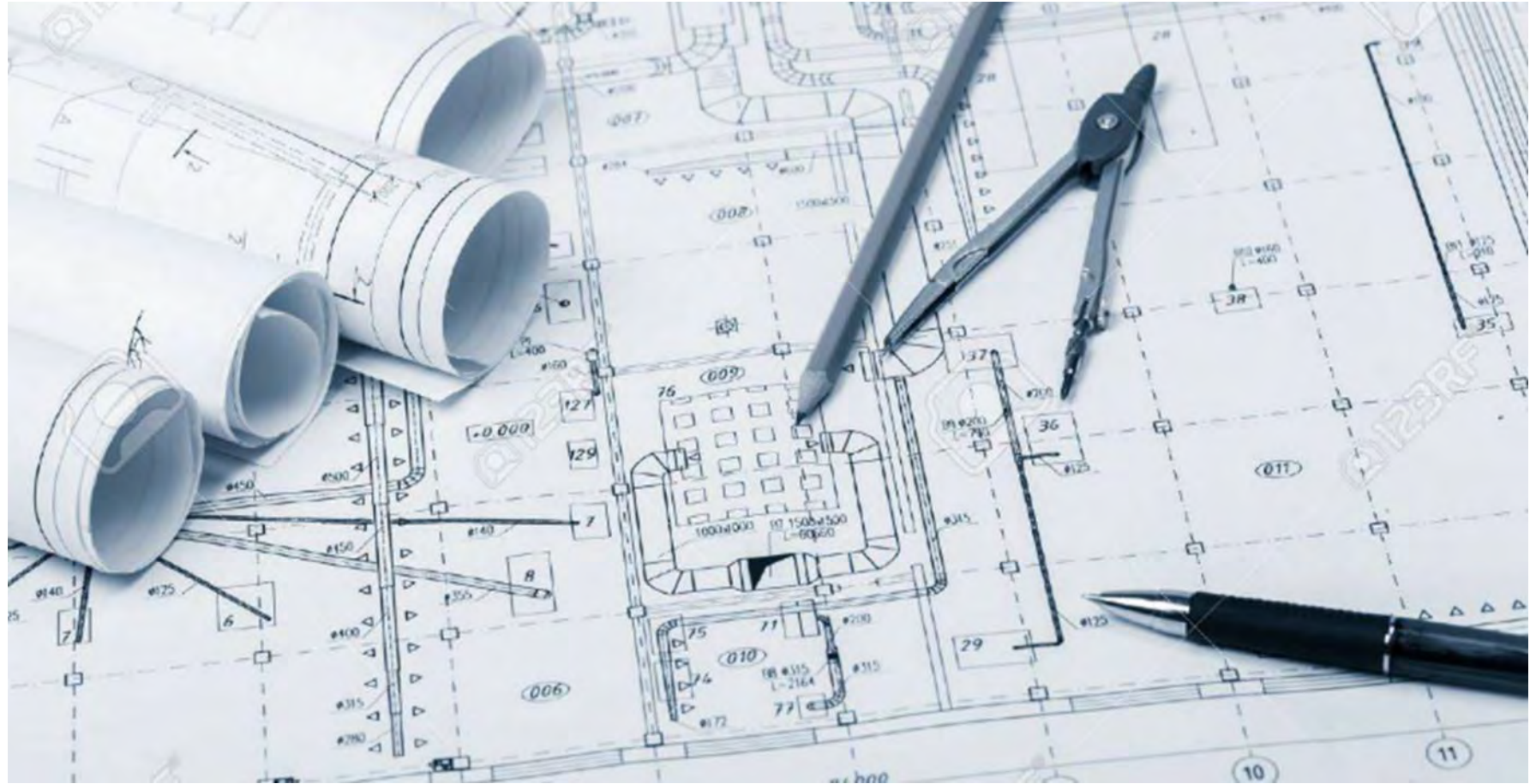*Are virtual audits merely a temporary tool to manage an emergent situation?*

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Polling Question

Do you currently think of virtual audits as:

- [ ] A temporary measure during the pandemic and potentially used in the future only when necessary.
- [ ] An approach that will be integrated into your audit program and how audits will be performed in the future.
- [ ] Don't know.

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Why Plan?

There are RISKS in forging ahead without planning.

- May underestimate the time and resources involved
- Lack of consistency in approach
- Mixed messaging to stakeholders and inability to manage expectations
- Dissatisfaction with the audit experience
- Lackluster results that come nowhere close to a site visit audit

Risks can be avoided by planning – or managed by integrating planning with the conduct of the virtual audits.

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Six Steps to Planning a Virtual Audit Program

Steps don't have to be done in this order.

Some steps can be worked in parallel.

1. Set clear objectives and manage expectations.
2. Determine the best allowable operational approach(es).
3. Investigate and decide which tech tools to use.
4. Establish a policy and procedure for virtual audits. Keep it simple.
5. Establish criteria for facility selection.
6. Decide how and when to launch the program.

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1. Set clear objectives and manage expectations.

- Why?
  - Establishes parameters which helps to manage expectations
  - Provides insights on the correct level of effort
- Guiding questions to set objectives:
  - Potential long-term change or a stop gap measure?
  - Intended to be equivalent to site visit audits or a supplemental performance check?
  - Full scope or limited scope?

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2. Determine the best allowable operational approach(es).

Operational approaches differ in how physical inspections and observations are conducted:

Approach	Description
Trusted Actor	Conducted indirectly through requested photos or status checks by a trusted individual at the site.
Tech Enabled	Conducted directly by the remote auditor using tech tools.
Local Auditor	Conducted by a skilled local surrogate such as a professional auditor from outside the organization who coordinates with the remote audit team.

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2. Determine the best allowable operational approach(es).

Examples of advantages and disadvantages of each approach:

Approach	Advantage	Disadvantage
Trusted Actor	Familiarity with facility layout and operations.	Familiarity with the landscape can lead to unintentional oversights.
Tech Enabled	Remote auditor can observe directly, in real time; If recorded, footage can be reviewed later.	Can give a false sense of assurance or unrealistic expectations about the thoroughness of the audit.
Local Auditor	Objective, independent auditor present onsite; conversant in local language.	Facility access and coverage will need to be negotiated and navigated.

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3. Investigate and decide which tech tools to use.
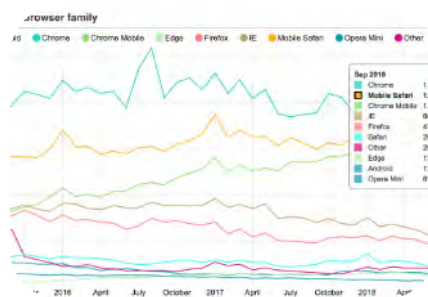

Communicate/ Collaborate

Visualize Site Conditions
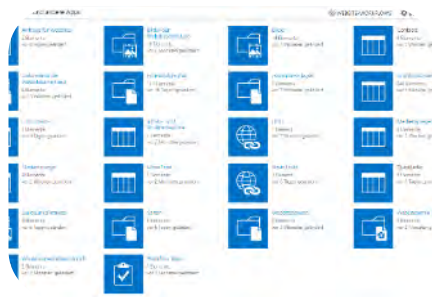
Manage Documents

Analyze Data

- Begin with what is readily available.
- Be mindful of security at all stages of data management.
- Consider the auditee's ability to effectively use the technology.
- Don't rush into significant technology investment.
  - Look for internal and external technology partners.
  - Thoroughly investigate rapidly evolving market.

4. Establish a policy and procedure. Keep it simple.

- *Provides a consistent approach >> meaningful results*
- *Sets the broad parameters*
- *Gets everyone on the same page*
- *Fosters continuous improvement*

Framework
- Objectives
- Authorization
- Allowable Approach and Technology

Process
- Roles and Responsibilities
- Pre-audit and Audit
- Reporting

Data and Quality
- Document and Information Management
- Audit Data Management
- Feedback and Continuous Improvement

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4. Establish a policy and procedure. Keep it simple.

Key areas where a virtual audit procedure varies from the site visit audit procedure...

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Potential New Roles to Define in Procedure

Lead Auditor Proxy

Role
- Coordinates on-site audit activities
- Liaises with remote lead auditor and site team

Qualities
- Familiar with the site
- Sufficient span of control
- Understands EHS audit process

Technology Coordinator

Role
- Make sure tools are in place and functional
- Test tools prior to use
- Train users

Qualities
- Familiar with technology being used
- Availability for rapid trouble-shooting

Scheduler

Role
- Schedule pre-audit and audit meetings
- Assists with on-site logistics as needed

Qualities
- Familiar with the site team
- Competent with virtual meeting platform
- Availability to schedule ad hoc meetings

Records Coordinator

Role
- Locate, scan, and upload requested documents
- Keep audit team informed of available documents

Qualities
- Familiar with site's EHS documents and records
- Competent with the electronic document platform

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Polling Question

In comparison to a traditional onsite audit, does your currently allocate:

❑ More time for the virtual audit process

❑ Less time for the virtual audit process

❑ Same amount of time for the virtual audit process

❑ Company does not conduct virtual audits

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Pre-audit Procedure

- Address in the procedure and build in sufficient lead time for these additional pre-audit milestones:
  - Intro to virtual audit procedure
  - Intro to auditing (if non-auditors are on the team)
  - Assignment of roles
  - Training on tech
  - Aids to fully orient remote auditors to site
- Attention to these pre-audit milestones will help the audit go forward more smoothly

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Feedback and Continuous Improvement

- Virtual audit procedure should provide for assessment of:
  - Outcomes in comparison with the objectives you set (remember those?)
  - The deliverables of the virtual audits (e.g., closing meeting and report)
  - The satisfaction of participants and management

Virtual Audit Program Planning

Adjust Virtual Audit Procedure

Conduct a Virtual Audit

Assess Results

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5. Establish criteria for facility selection.

- Begin with high performing sites where participants:
  - Tend to be more patient and open to communications
  - Are familiar with requirements and actively seek feedback
  - Are more likely to provide useful and truthful feedback
- In the beginning, consider avoiding sites where participants:
  - Have a track record of resistance to audits
  - Are not experienced with the regular EHS audit program or auditing in general

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6. Decide how and when to launch the program.

- If you haven't already started virtual auditing:
  - Consider tracking cost and level of effort
  - Brief management and sites on the plan
- If you have started consider taking a pause to:
  - Fully evaluate how they functioned and to think about how the program will be carried forward.
  - Adjust and fill in any gaps in the program plan.
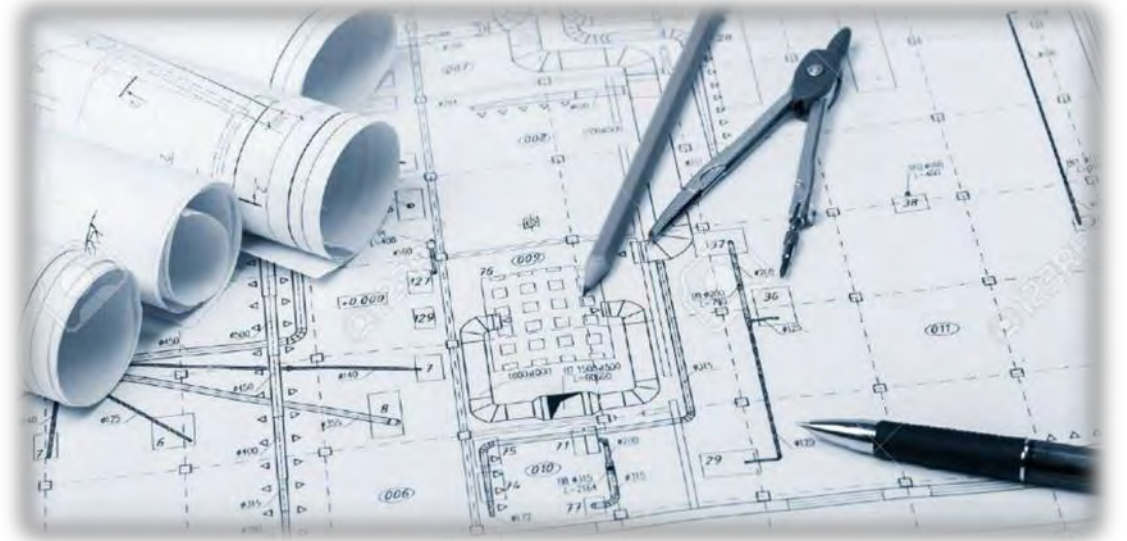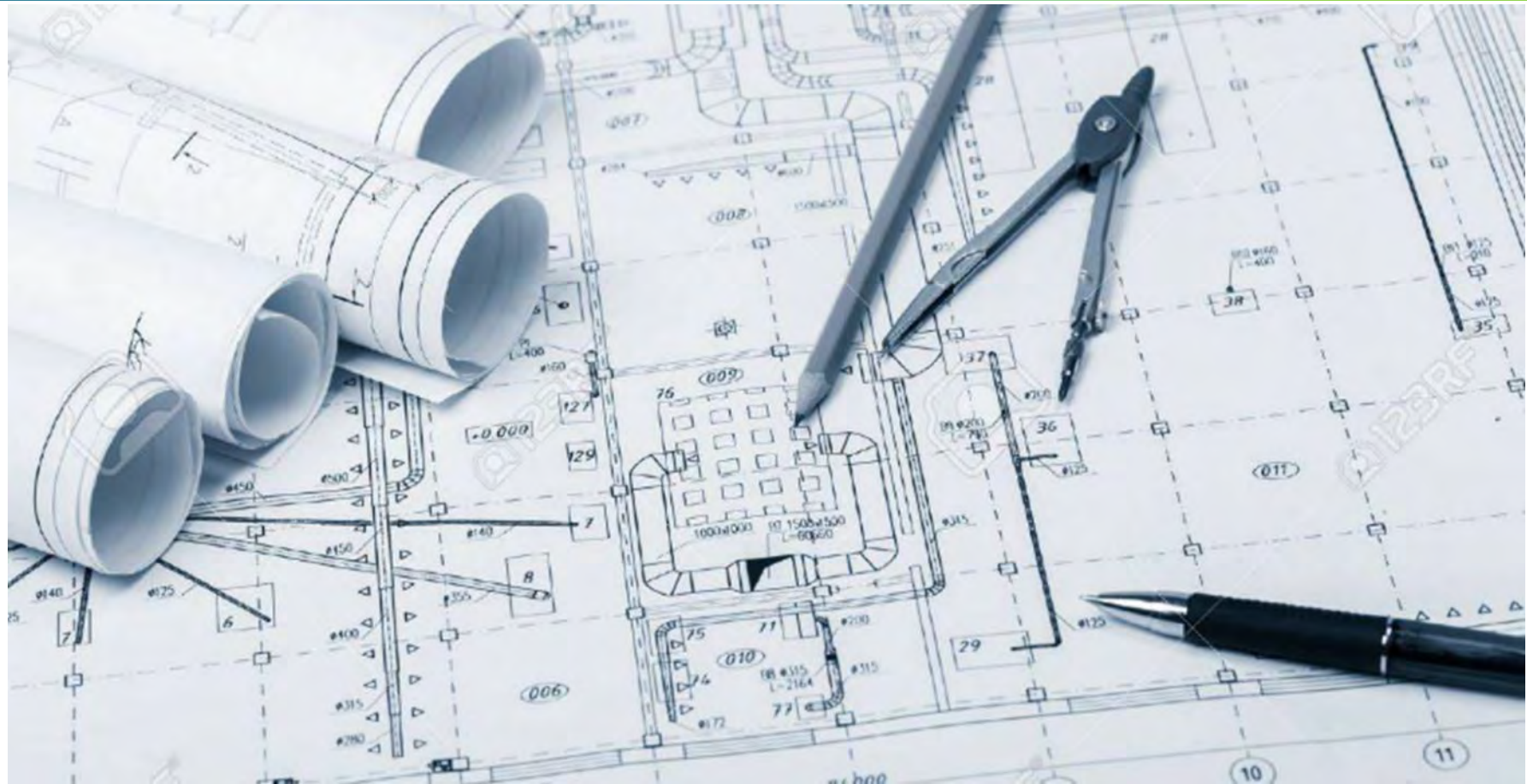
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CLOSING THOUGHTS

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Download from:

www.cc-global.com

Watch for an **updated version** in August.

There is much more information in the white paper about planning and executing virtual audits.

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Q&A SESSION

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Thank You

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