

*A Graded Approach to  
Assuring Quality*

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## What is a graded approach?

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- Does a graded approach mean not meeting applicable requirements?
- Does graded approach mean applying adequate rigor based on the risk of failure?
- Is graded approach an over used term without meaning?

# Here is what the EPA says about “Graded Approach”

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- “EPA recognizes that a “one size fits all” approach to quality specifications will not work. Therefore, the implementation of the EPA Quality System is based on a graded approach. A graded approach means that quality systems for different organizations and programs will vary according to the specific objectives and needs of the organization. For example, the quality practices needed in a research program are different from those in a regulatory compliance program because the purpose or intended use of the data is different.”
  - <http://www.epa.gov/quality/internal.html#graded>

“Graded Approach” is applying adequate rigor based on planned use

- In an environmental remediation setting this could be selecting one analytical method over another to obtain the needed accuracy and precision
- In manufacturing, it could be specifying the needed tolerance without over specifying
- In document control it may be requiring only the needed reviews, not everybody

## One specific example of assuring quality using a graded approach

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- Some companies perform a receiving inspection on incoming materials and supplies
  - If you simply need to confirm the part number is what you ordered, the receiving can be simplified and throughput increased
  - On complex, engineered, unique items critical dimensions and testing of the product before use may be necessary

## One specific example of assuring quality using a graded approach

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- By looking at the part number only for those items purchased by part number:
  - the talents of the inspectors are better spent on the more complex items that need the more rigorous evaluation
  - Items are provided to the projects quicker increasing production without compromising quality
  - Manpower needs are reduced because everything received does not need a detailed inspection.

## Let's clarify requirements use

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- If your company is hiring another to complete work, how do you specify the requirements to the supplier?
  - You would not impose a set of design requirements if the supplier was not designing for you
  - You might not require the supplier to maintain a quality assurance program if that supplier is providing commerce, off-the-shelf equipment.

## Let's clarify requirements use

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- If your company is hiring another to complete work, how do you specify the requirements to the supplier?
  - If the company had a registered ISO program, you may not need to complete an on-site audit
  - You may require an independent review of the order if the product is simple or an “off-the-shelf” product

## What graded approach is NOT!

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- Taking a graded approach is not meeting only a part of the appropriate requirements
- Taking a graded approach is not bypassing defined processes to “get er done” quicker
- Violating regulations to complete a task on time

## So, what is a graded approach?

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- Applying only those requirements that apply to the work or product.
- Doing only the inspections required or needed to assure the adequacy of the product.
- Recognizing that “one size does not fit all.”

# Questions?

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- Are there any questions?