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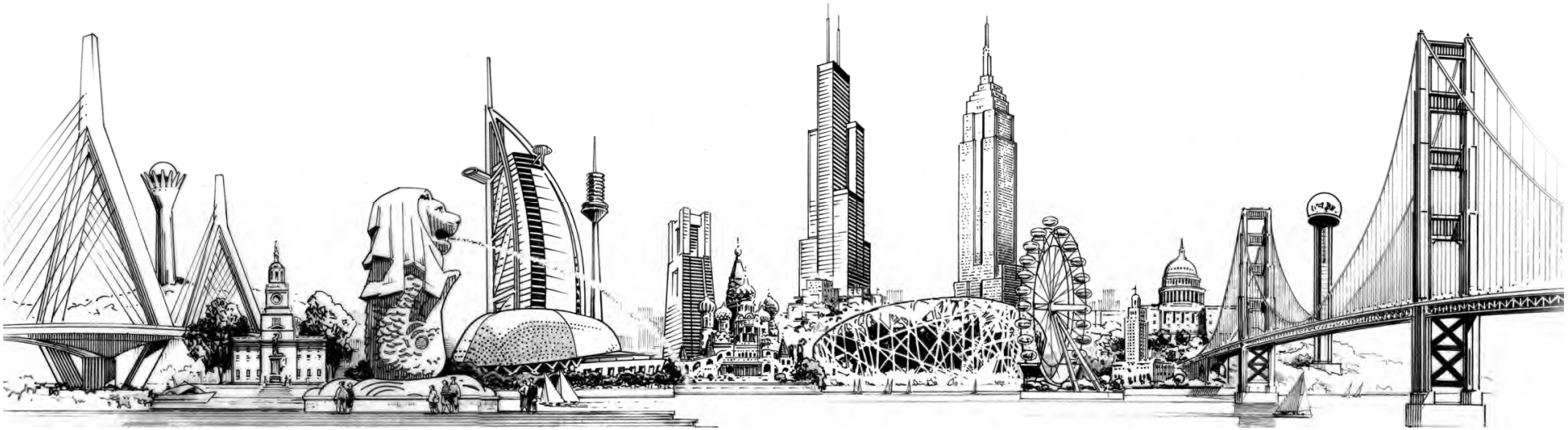
# NRC REPORTING REQUIREMENTS IN PART 21

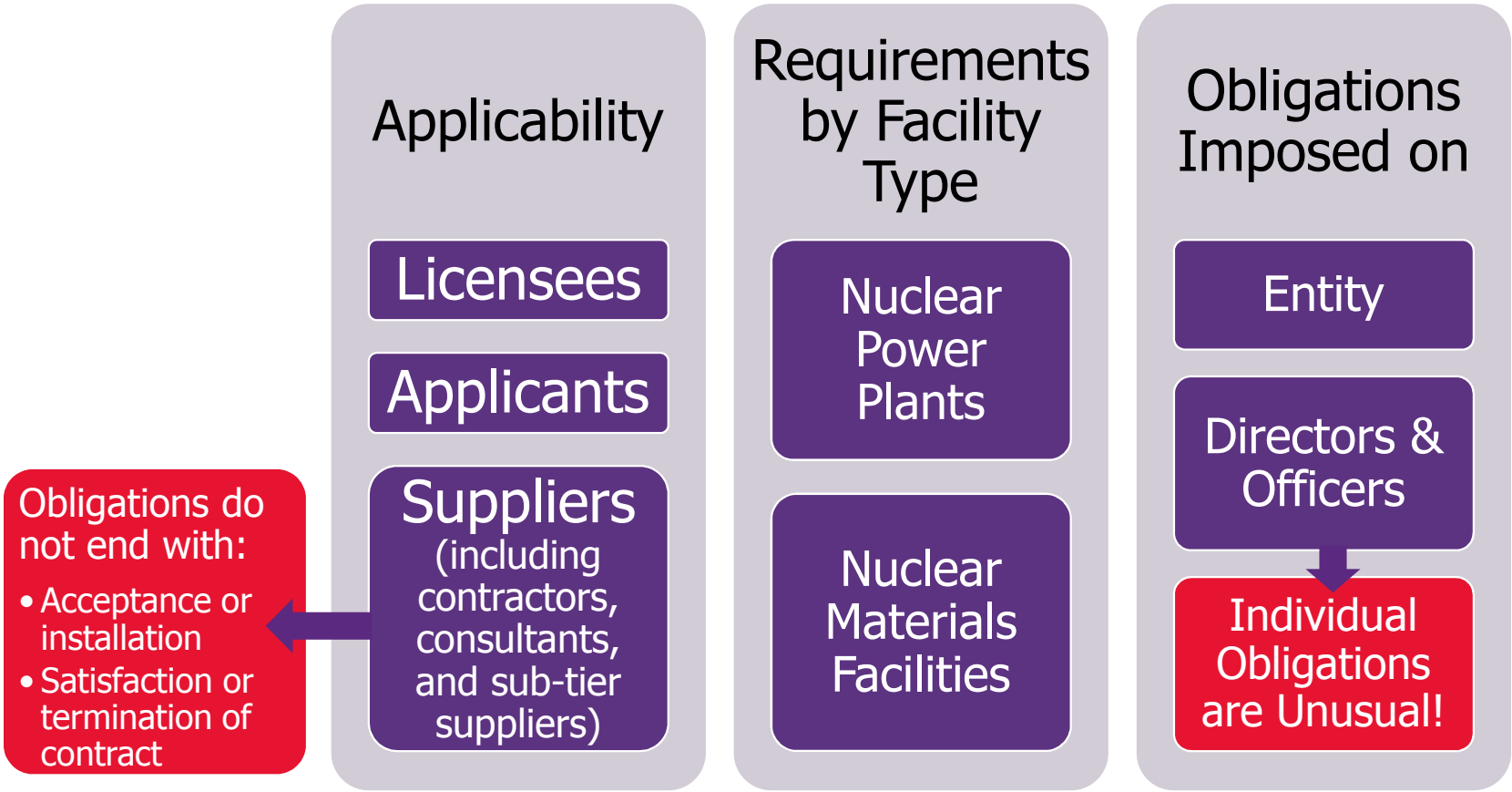
Steven P. Frantz
Ryan K. Lighty

July 28, 2015



# Background on 10 C.F.R. Part 21

Part 21 implements Section 206 of the Energy Reorganization Act of 1974 (42 U.S.C. § 5846, et seq.)

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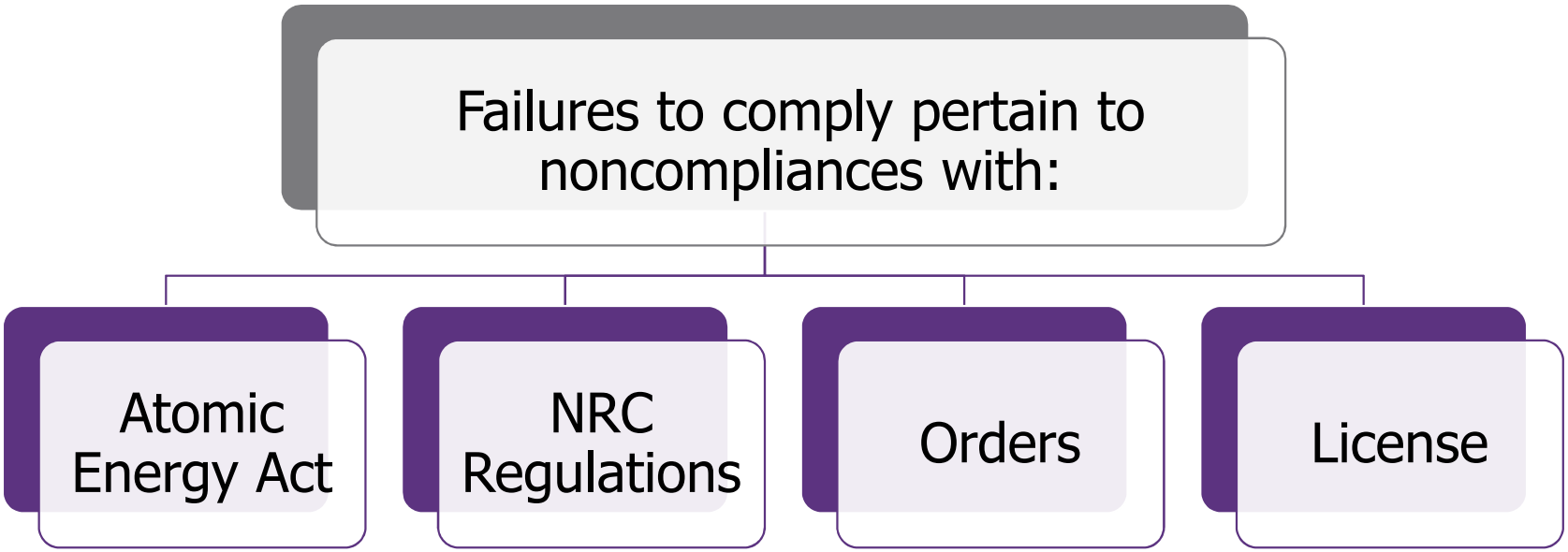
# Reportable Conditions

Part 21 Requires Reporting of the Following to the NRC:

1. Defects in basic components that could create a substantial safety hazard
2. Failures to comply affecting manufacture, construction or operation of a facility or an activity that is subject to the licensing requirements and that could create a substantial safety hazard

Reporting is required even if the component in question has been delivered but never installed or used

# Failure to Comply




Failures to comply do not pertain to codes and standards or guidance documents, except to the extent incorporated into the requirements listed above

# Substantial Safety Hazard

A substantial safety hazard is a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety (assuming the condition remains uncorrected).

Examples:

| | |
|---|---|
| *Moderate exposure* to, or release of, licensed material | • Exposure in excess of 25 rems whole body<br>• Releases to or exposure of an individual in an unrestricted area to more than Part 20 limits (e.g., 0.5 rem) |
| *Major degradation* of essential safety-related equipment | • A loss of redundancy if, in conjunction with a single failure, a required safety function could not be performed |
| *Major deficiencies* involving design, construction, inspection, test, or use of licensed materials or facilities | • A condition or circumstance which under normal operating conditions or anticipated transient could contribute to exceeding a safety limit or cause an accident<br>• A deficiency which seriously compromised the ability of a confinement system to perform its designated function |

The loss of safety function of a basic component is reportable, even if a redundant component exists

# Basic Components

- In nuclear power plants, basic components are safety-related components that are subject to the Quality Assurance (QA) requirements in Appendix B to Part 50; *i.e.*, components needed for:
  - The integrity of the reactor coolant pressure boundary;
  - The capability to shut down the reactor and maintain it in a safe-shutdown condition; or
  - The capability to prevent or mitigate the consequences of design basis accidents
- Basic components include services, such as design, inspection, testing, or consulting services for basic components
- Basic components also include security systems to the extent failure could result in a substantial safety hazard
- Integral parts of basic components may or may not be basic components, depending upon their impact on safety-related functions
- An isolated defect in a batch of basic components is reportable

# Commercial Grade Items (CGIs)

- CGIs are components and equipment that are not designed and manufactured in accordance with an Appendix B QA program
  - A CGI is not classified as basic component until such time as the item is *dedicated* for use as a basic component
  - There are specific criteria governing the dedication process, including requirements for verification of critical characteristics
  - Once a CGI is dedicated as a basic component, it is deemed equivalent to an item designed and manufactured under an Appendix B QA program
- The supplier of a CGI has no obligations under Part 21
- The dedicating entity and subsequent purchasers have obligations under Part 21
- Some CGIs cannot be dedicated; e.g., components for which:
  - the design and manufacturing process requires in-process inspection;
  - one or more critical characteristics cannot be verified later

# Defects

| | Five Definitions | Focus |
|---|---|---|
| 1 | A deviation in a basic component delivered to a purchaser for use in a facility if the deviation could create a substantial safety hazard; | supplier who delivers a basic component |
| 2 | The installation, use, or operation of a basic component containing a defect; | a purchaser who accepts a basic component |
| 3 | A deviation in a portion of a facility that could create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; | onsite architect/engineer or constructor who has delivered its product to the plant owner |
| 4 | A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit as defined in the technical specifications; | operator |
| 5 | An error, omission or other circumstance in a design certification that could create a substantial safety hazard. | design certification applicant and its suppliers |

# Deviation

**Deviation**:

*a departure from the technical requirements*

*included in a procurement document…*

- A counterfeit or fraudulent part is a deviation but is not necessarily a defect
  - Evaluation is needed to determine whether the part could create a substantial safety hazard
  - If the deviation is not associated with a substantial safety hazard, the counterfeit or fraudulent part is not reportable under Part 21

    Additional discussion in RIS-2015-08, "Oversight of Counterfeit, Fraudulent, and Suspect Items in the Nuclear Industry" (June 24, 2015)

# Evaluations of Deviations and Failures to Comply

- Upon *discovery* of a deviation or failure to comply, the company must:
  - Perform an evaluation to determine whether it involves a substantial safety hazard if it were to remain uncorrected; and
    - Complete the evaluation within 60 days of *discovery*; or
    - Make an interim report to the NRC.
- A supplier may not have the capability to determine whether the component or service it supplied involved a substantial safety hazard
  - In such cases, the supplier must inform the purchaser, who must then perform the evaluation
  - Notification of the purchaser must occur within 5 days from when supplier determines it cannot make the determination
- If a supplier finds a deviation in an undelivered component, it should evaluate whether similar deviations exist in delivered components

# Discovery

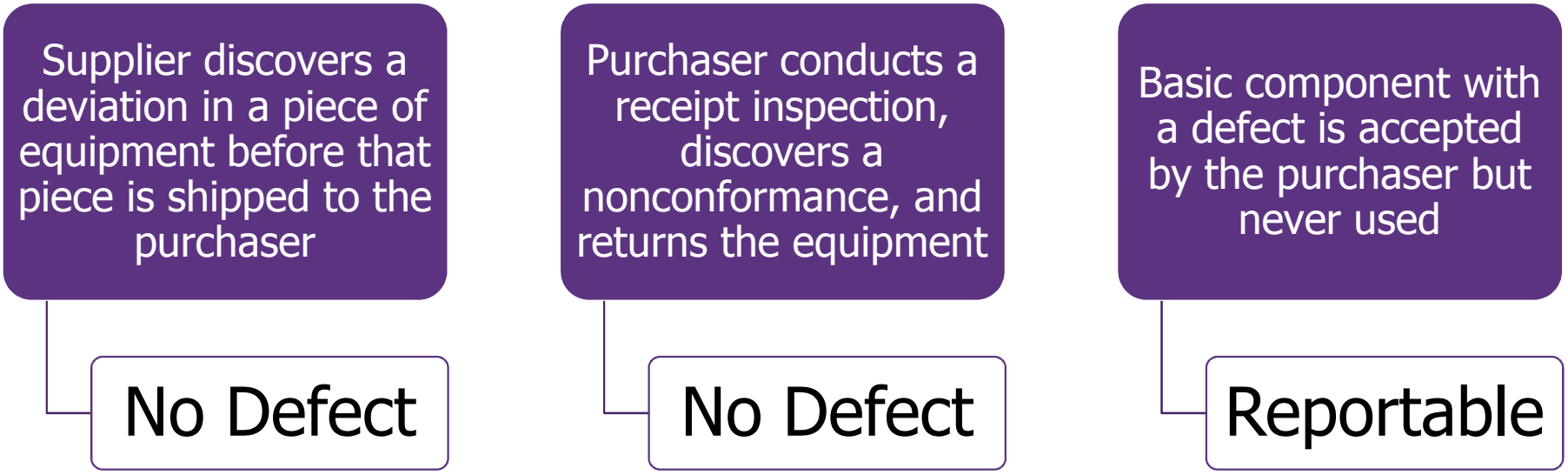
- 60-day obligation to evaluate begins upon discovery
  - Discovery means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard (10 CFR 21.3)
- Potential deviations do not trigger the 60-day evaluation period, but should be reviewed without delay to determine if a deviation exists

**NRC's draft regulatory basis** states that discovery occurs when a deviation or failure to comply is **first documented in the corrective action program**

In contrast, **NEI 14-09** states **some review must occur prior to the point of discovery** to determine whether the failure is potentially associated with a substantial safety hazard

# Delivery

- A defect can exist only upon delivery of the component or service
- NRC's draft regulatory basis states that delivery occurs when the purchaser has accepted a basic component through a formal process, such as receipt inspection
- NEI 14-09 has a similar provision



# International Applicability of Part 21

# Exceptions to Reporting under Part 21

- 10 C.F.R. § 21.21(d)(2): Reporting to NRC is not required if NRC has been previously notified in writing of the defect or failure to comply
- 10 C.F.R. § 21.2(c): Evaluation and reporting of potential defects under 10 C.F.R. §§ 50.72 and 50.73 also satisfies the evaluation and reporting requirements in Part 21

| NRC Draft Regulatory Basis | NEI 14-09 |
| --- | --- |
| • 10 C.F.R. § 21.2(c) applies only if the potential defect is actually reported under 10 C.F.R. §§ 50.72 or 50.73<br>• If the potential defect is evaluated but not reported under 10 C.F.R. §§ 50.72 and 50.73, the potential defect must be evaluated for reportability under Part 21 | • for events evaluated under 10 C.F.R. §§ 50.72 or 50.73, a separate evaluation under Part 21 is not necessary |

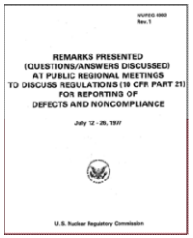
# Requirements Related to Timing (§ 21.21)

| | |
|---|---|
| Upon discovery of a deviation or failure to comply | 60 days for an evaluation |
| Upon determination of a reportable condition | 5 working days to notify the director or responsible officer |
| Upon notification of the director or responsible officer: | 2 days to make an oral notification to NRC<br>30 days to submit written report to the NRC |

# Other Requirements in Part 21

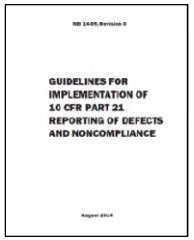
| Procurement Documents | Procedures | Posting | Recordkeeping |
|---|---|---|---|
| **§ 21.31** | **§ 21.21** | **§ 21.6** | **§ 21.51** |
| • Procurement documents for basic components must reference Part 21<br><br>*Per NEI 14-09, Part 21 applies to a supplier even if the procurement document does not reference Part 21 if the supplier knows it is supplying a basic component.* | • Companies must have procedures for implementing Part 21 | • Companies must post Section 206 of the Energy Reorganization Act, Part 21, and implementing procedures<br><br>• Posting must be in a conspicuous position<br><br>• Electronic posting is permissible | • Companies must maintain records and allow NRC inspection |

# Guidance on Part 21




## NRC Guidance

- NUREG-0302, Rev. 1, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance" (July 1977)
- Additional guidance in responses to questions at 2008 Workshop
- Collectively, does not address some of NRC's current interpretations




## Nuclear Energy Institute (NEI) Guidance

- NEI 14-09, Rev. 0, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance" (Aug. 2014)
- Currently being reviewed by NRC Staff

NRC is planning a rulemaking and a new guidance document to clarify the provisions in Part 21

- NRC has issued a Draft Regulatory Basis for the rulemaking
- Some of NRC's clarifications are different than the positions in NEI 14-09

# NRC Plans for Rulemaking on Part 21


- NRC desires to codify some of their current interpretations of Part 21

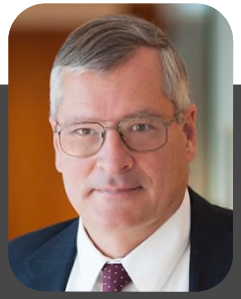
**2016**: Proposed Rule & Draft Regulatory Guide (DG-1291)*

**2018**: Final Rule & Regulatory Guide

* *DG-1291 could endorse NEI 14-09 (with some modifications or exceptions)*

- NEI has objected to the rulemaking
  - Has requested NRC to endorse NEI 14-09 instead of engaging in rulemaking

# Contact Information




Steven P. Frantz
sfrantz@morganlewis.com
+1 202.739.5460



Ryan K. Lighty
rlighty@morganlewis.com
+1 202.739.5274

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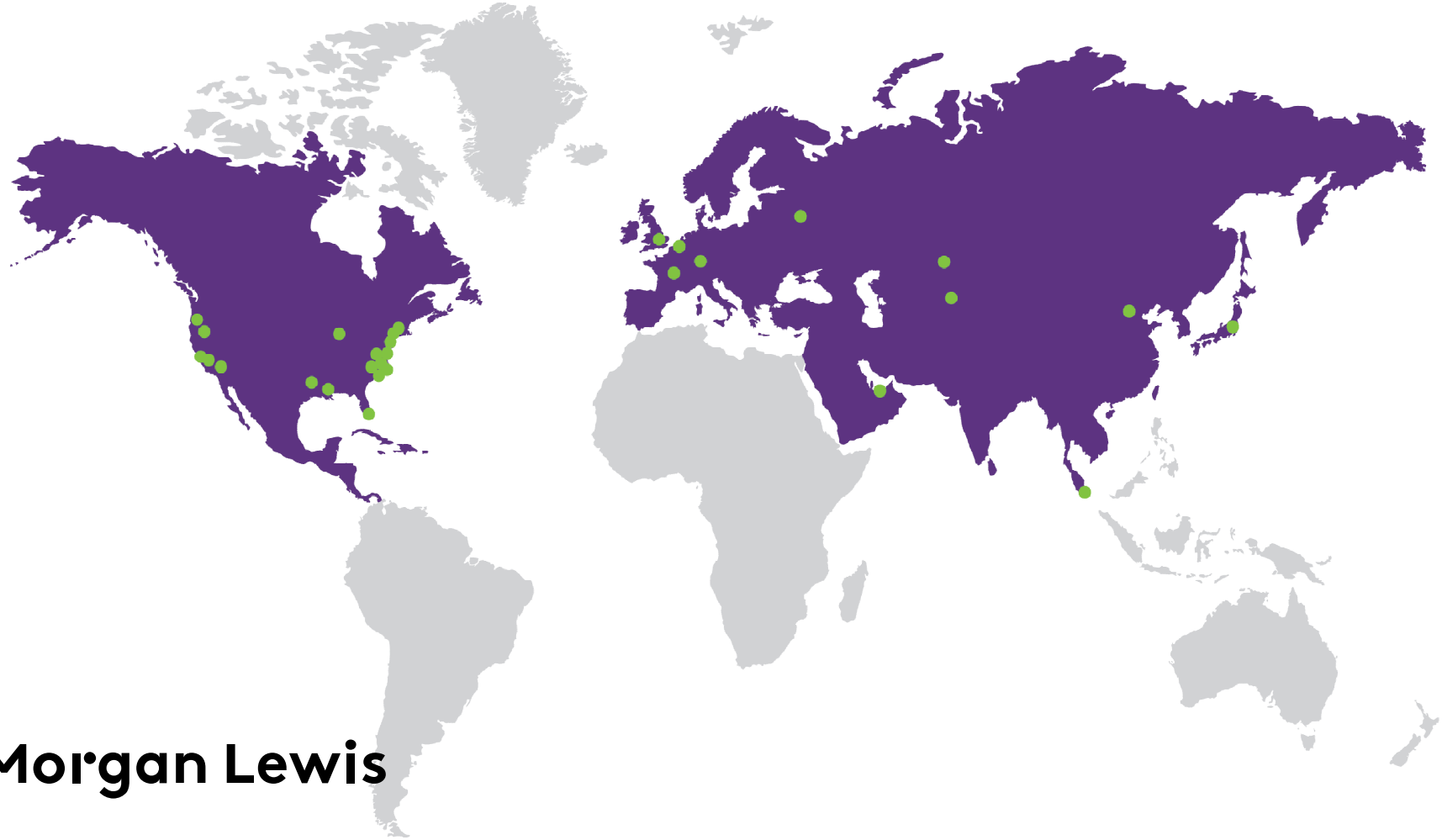

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# THANK YOU