

Preparing for Regulatory Inspections.
It isn't a question of if, but when.
Office of Research Compliance

Preparing for REGULATORY INSPECTION

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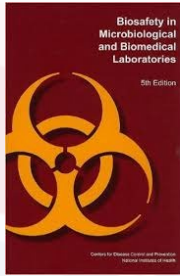
Disclaimer

The opinions expressed are those of the presenters and may not necessarily reflect Montana State University.



Regulatory Oversight and Inspections

Examples of Regulatory Oversight:



2021 MSU Inspections:

- 2 CDC Inspections for Select Agent Program
- 1 CDC Inspection for imported material work
- 1 NRC Inspection for Radiation program
- 1 USDA inspections for Animal Care & Use Program

COMPLIANCE

TRANSPARENC

RULES

POL


GULATIONS

STANDARDS


REQUIREM

Office of
Research
Compliance
Areas


Biosafety



Animal Care
and Use



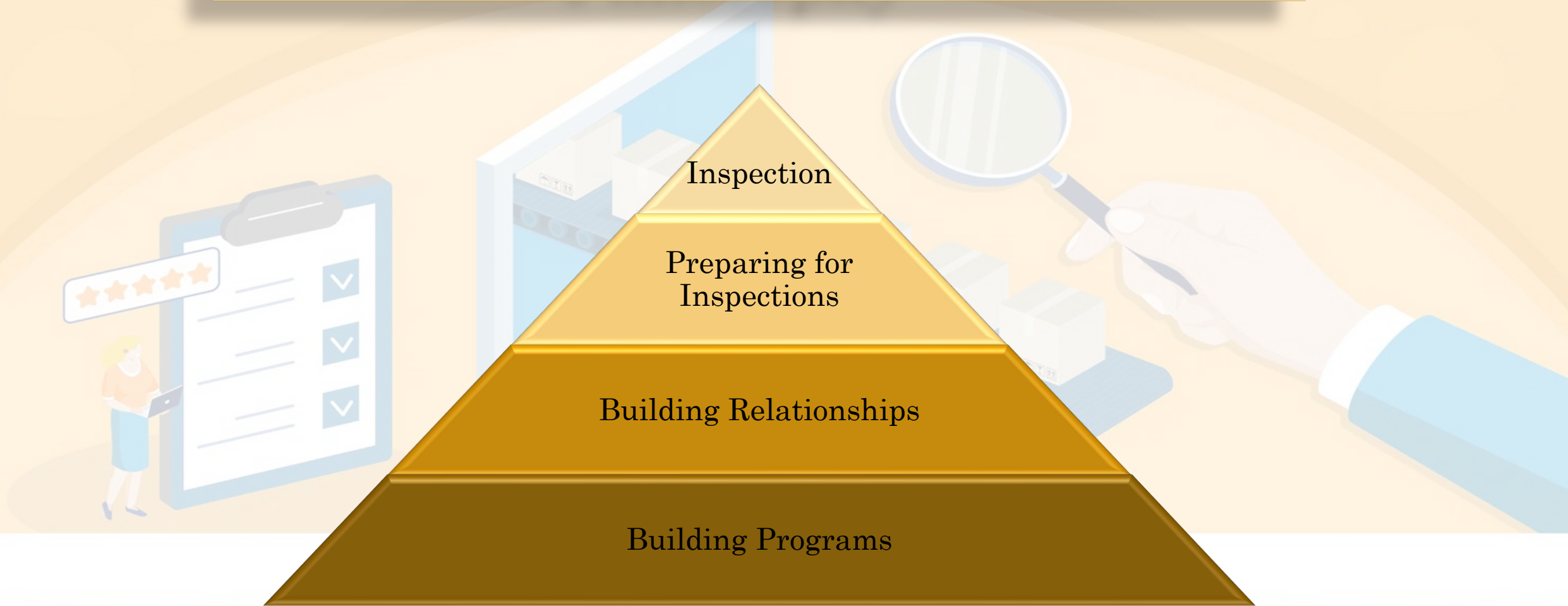
Radiation
Safety



Human
Subject
Research



Overall Inspection and Program Philosophy

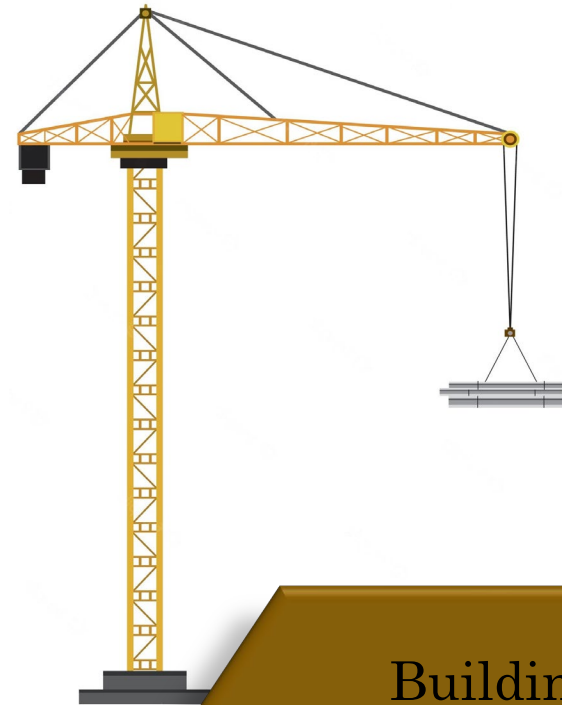


Inspection Ready – Building Programs

Know the Regs

Trust your Subject Matter
Expert and Team

Be Two Deep



Building Programs

Inspection Ready – Building Programs

Create a Rhythm

User Friendly Policies

Does it Add Value?


Listen to Your Stakeholders



Building Programs

Building Relationships

- Build staff, laboratorian, PI relationships
- If possible, develop a relationship with inspectors/agencies
- Attend the agency webinars and training
- Ask for guidance
- If required, self-report



Building Relationships

Building Programs

Preparing for Inspections

- Conduct self inspections
- Ask inspectors for a pre-inspection meeting
- Appoint a point person and secondary personnel to assist during the inspection
- Communicate inspection with upper administration



During the Inspection

Have records easily available
for inspectors

Provide requested documents
in a timely manner

Only answer the question



During the Inspection

If you don't know, just say you don't know

Be available for communication

Provide information



Post Inspection Wrap Up

- If you need to, push back on a finding interpretation
- Respond to findings
- Conduct self-analysis
- Communicate



Thank You!

Questions?

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