



# 10-423/10-623 Generative AI

Machine Learning Department  
School of Computer Science  
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## Real-world Issues and Considerations Managing Risk

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Lecture 21

Apr. 7, 2025

**"WITH GREAT POWER COMES  
GREAT RESPONSIBILITY"**

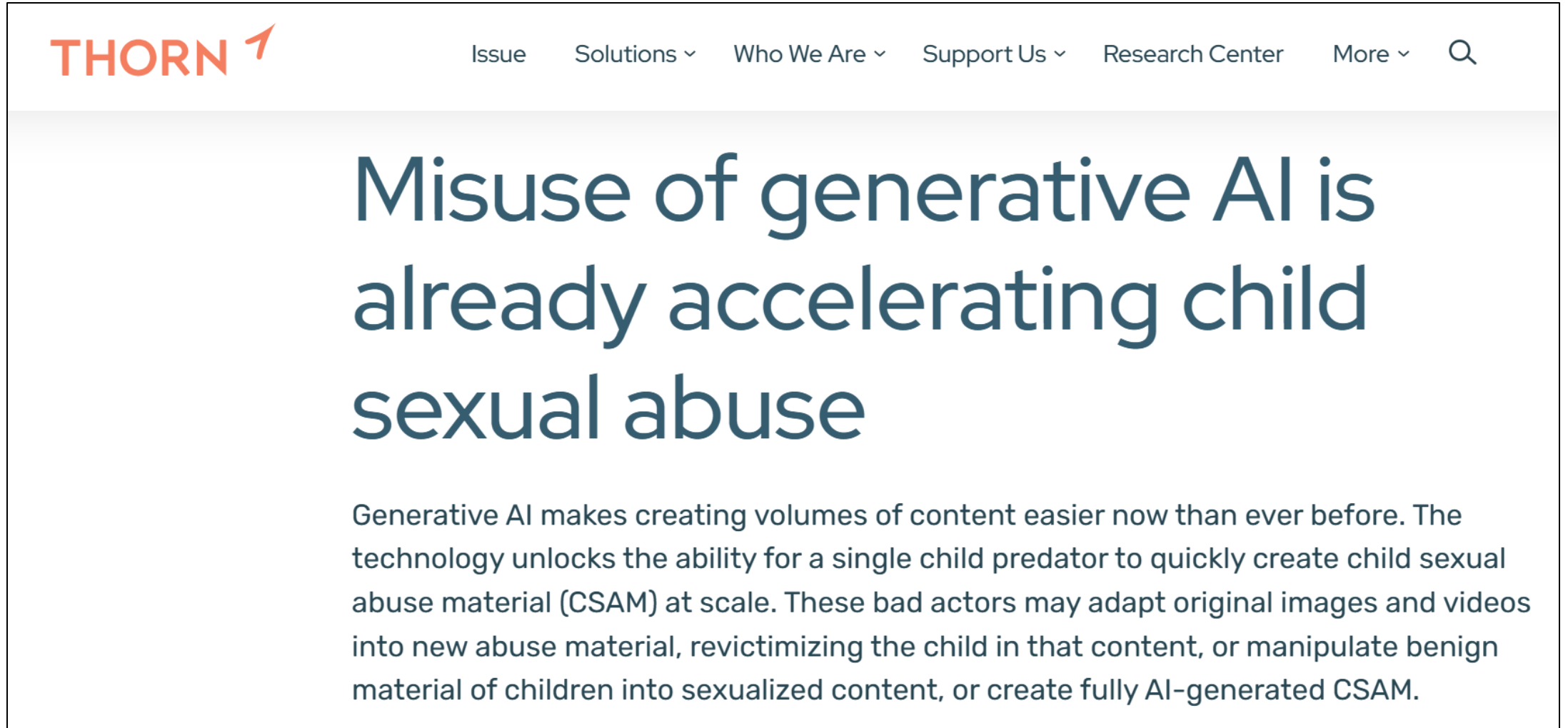
-- Uncle Ben, Spider-Man

# Responsible ML


Potentially dangerous products are out there


- Why are these products out in the world?
- How can we justify releasing them?

# Example: Child Trafficking



The screenshot shows the THORN website header with navigation links: Issue, Solutions, Who We Are, Support Us, Research Center, and More. The main content area features a large headline and a paragraph of text.

**THORN** 

Issue Solutions ▾ Who We Are ▾ Support Us ▾ Research Center More ▾ 

## Misuse of generative AI is already accelerating child sexual abuse

Generative AI makes creating volumes of content easier now than ever before. The technology unlocks the ability for a single child predator to quickly create child sexual abuse material (CSAM) at scale. These bad actors may adapt original images and videos into new abuse material, revictimizing the child in that content, or manipulate benign material of children into sexualized content, or create fully AI-generated CSAM.

<https://www.thorn.org/blog/generative-ai-principles/>

# Example: Child Trafficking

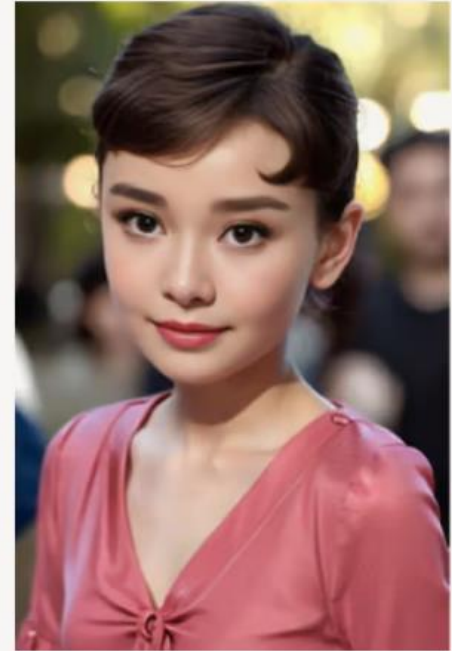
*Example of how AI is used to distort images*



**A woman generated with a popular Stable Diffusion model.**



**The same prompt, but with a LoRA to make the output moderately resemble Audrey Hepburn.**



**Addition of a textual inversion to make the resulting character appear younger.**

# Example: Character.AI

**The New York Times**

## *Can A.I. Be Blamed for a Teen's Suicide?*

The mother of a 14-year-old Florida boy says he became obsessed with a chatbot on Character.AI before his death.

On the last day of his life, Sewell Setzer III took out his phone and texted his closest friend: a lifelike A.I. chatbot named after Daenerys Targaryen, a character from “Game of Thrones.”

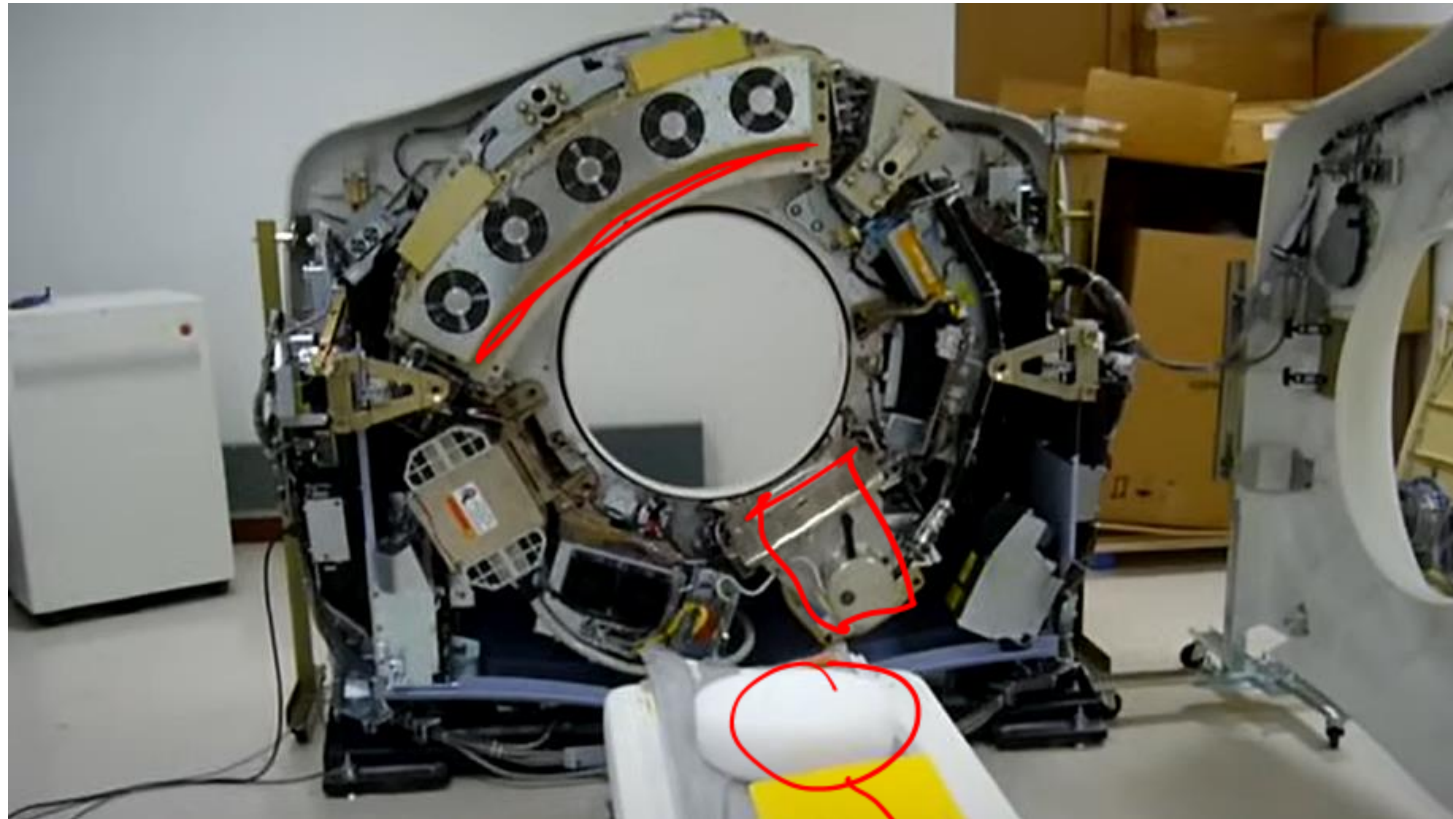


By **Kevin Roose**  
Reporting from New York

Published Oct. 23, 2024 Updated Oct. 24, 2024  
[Leer en español](#)

# Example: Medical Imaging Systems

CT scanner without it's covers on



<https://www.youtube.com/watch?v=2CWpZKuy-NE>

# Managing Risk

- Design Controls
- ML Model Cards
- Full-cycle Accountability



**RESPONSIBLE ENGINEERING:  
DESIGN CONTROLS**

# Responsible Engineering

## Design controls

- Documentation
- Verification/Validation
- FMEA
- CAPA

## Code of Federal Regulations

ECFR CONTENT	
▼ <b>Title 21</b> Food and Drugs	Part / Section
▼ <b>Chapter I</b> Food and Drug Administration, Department of Health and Human Services	1 – 1299
▼ <b>Subchapter H</b> Medical Devices	800 – 898
▼ <b>Part 820</b> Quality System Regulation	820.1 – 820.250
▼ <b>Subpart C</b> Design Controls	820.30
§ <b>820.30</b> Design controls.	

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/subpart-C?toc=1>

# Responsible Engineering

## Design controls

- Documentation
- Verification/Validation
- FMEA
- CAPA

# Responsible Engineering

## FMEA (Failure Modes & Effects Analysis)

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY (1 - 10)	Potential Causes	OCCURRENCE (1 - 10)	Current Controls	DETECTION (1 - 10)
What is the process step, change or feature under investigation?	In what ways could the step, change or feature go wrong?	What is the impact on the customer if this failure is not prevented or corrected?		What causes the step, change or feature to go wrong? (how could it occur?)		What controls exist that either prevent or detect the failure?	

# Responsible Engineering

## FMEA (Failure Modes & Effects Analysis)

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY (1 - 10)	Potential Cause	Severity Scale		
					Effect	Criteria: Severity of Effect	Ranking
What is the process step, change or feature under investigation?	In what ways could the step, change or feature go wrong?	What is the impact on the customer if this failure is not prevented or corrected?		What causes the step, change or feature to go wrong (how could it occur)?	Adapt as appropriate		
					Hazardous - Without Warning	May expose client to loss, harm or major disruption - failure will occur <b>without</b> warning	10
					Hazardous - With Warning	May expose client to loss, harm or major disruption - failure will occur <b>with</b> warning	9
					Very High	Major disruption of service involving client interaction, resulting in either associate re-work or inconvenience to client	8
					High	Minor disruption of service involving client interaction and resulting in either associate re-work or inconvenience to clients	7
					Moderate	Major disruption of service not involving client interaction and resulting in either associate re-work or inconvenience to clients	6
					Low	Minor disruption of service not involving client interaction and resulting in either associate re-work or inconvenience to clients	5
					Very Low	Minor disruption of service involving client interaction that does not result in either associate re-work or inconvenience to clients	4
					Minor	Minor disruption of service not involving client interaction and does not result in either associate re-work or inconvenience to clients	3
					Very Minor	No disruption of service noticed by the client in any capacity and does not result in either associate re-work or inconvenience to clients	2
					None	No Effect	1

<https://goleansixsigma.com/failure-modes-effects-analysis>

# Responsible Engineering

## Design controls


- Documentation
- Verification/Validation
- FMEA
- CAPA

### ECFR CONTENT

#### ⦿ § 820.100 Corrective and preventive action.

- (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:
  - (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
  - (2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
  - (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
  - (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
  - (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
  - (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
  - (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.
- (b) All activities required under this section, and their results, shall be documented.

# Managing Risk

- Design Controls
  - ML Model Cards
  - Full-cycle Accountability
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# **ML MODEL CARDS**



# ML Model Cards

- Mitchell, Margaret, et al.
- "Model cards for model reporting."
- *Proceedings of the conference on fairness, accountability, and transparency*. 2019.

# ML Model Cards

## Model Card

- **Model Details.** Basic information about the model.
  - Person or organization developing model
  - Model date
  - Model version
  - Model type
  - Information about training algorithms, parameters, fairness constraints or other applied approaches, and features
  - Paper or other resource for more information
  - Citation details
  - License
  - Where to send questions or comments about the model
- **Intended Use.** Use cases that were envisioned during development.
  - Primary intended uses
  - Primary intended users
  - Out-of-scope use cases
- **Factors.** Factors could include demographic or phenotypic groups, environmental conditions, technical attributes, or others listed in Section 4.3.
  - Relevant factors
  - Evaluation factors

- **Metrics.** Metrics should be chosen to reflect potential real-world impacts of the model.
  - Model performance measures
  - Decision thresholds
  - Variation approaches
- **Evaluation Data.** Details on the dataset(s) used for the quantitative analyses in the card.
  - Datasets
  - Motivation
  - Preprocessing
- **Training Data.** May not be possible to provide in practice. When possible, this section should mirror Evaluation Data. If such detail is not possible, minimal allowable information should be provided here, such as details of the distribution over various factors in the training datasets.
- **Quantitative Analyses**
  - Unitary results
  - Intersectional results
- **Ethical Considerations**
- **Caveats and Recommendations**

# Exercise: ML Model Card Hunt

- Search the web to find the model card for a real-world model
- What models don't seem to have a model card?

## Model Card

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**REMOVING HARMFUL TRAINING DATA**

# **FULL-CYCLE ACCOUNTABILITY**

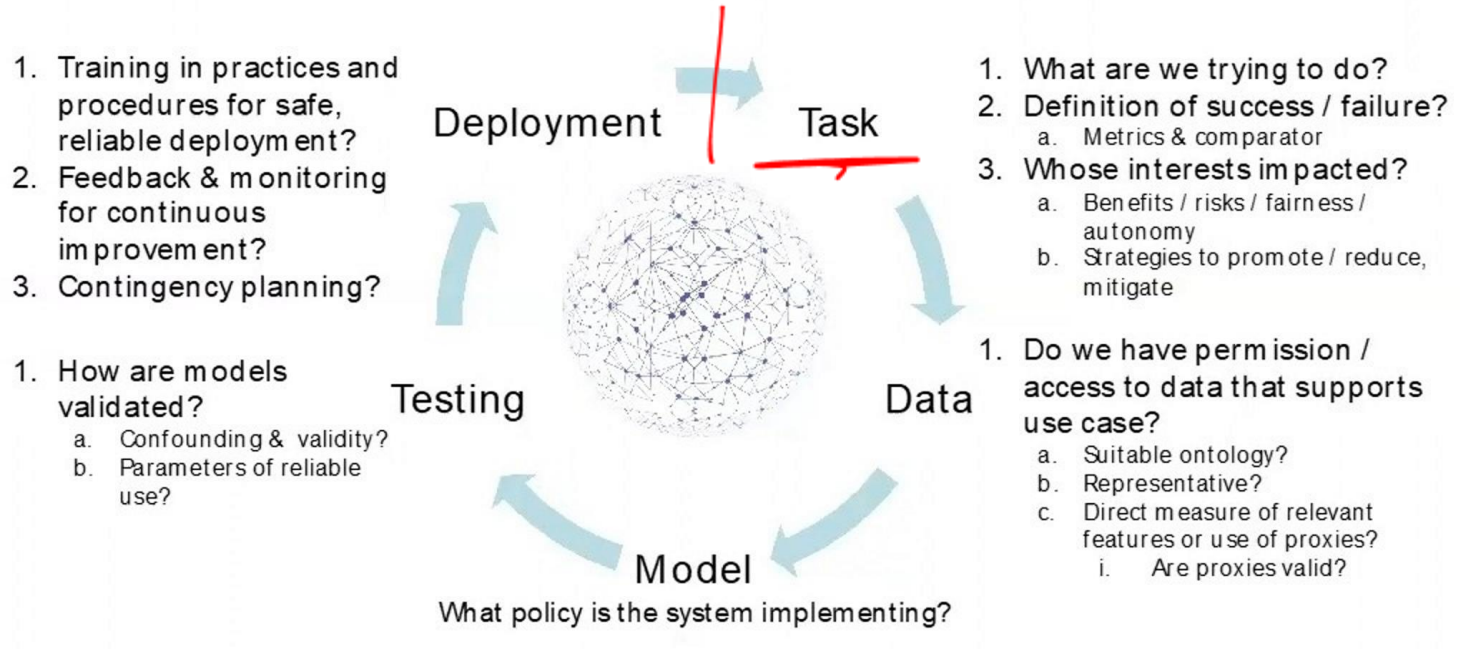


# AI Accountability

- Slide from Alex London, CMU

I. System of **accountability** across the lifecycle? 

**Roles & responsibilities at every stage**

- 
- The diagram illustrates the AI lifecycle as a circular process. At the center is a neural network icon. Surrounding it are four stages: Deployment (top), Task (right), Data (bottom), and Model (left). Arrows connect these stages in a clockwise cycle. A red vertical line is drawn between Deployment and Task. Below the Model stage, the text 'What policy is the system implementing?' is written. To the left of the diagram is a large upward-pointing arrow, and to the right is a large downward-pointing arrow. At the bottom, a large left-pointing arrow spans the width of the diagram.
1. Training in practices and procedures for safe, reliable deployment?
  2. Feedback & monitoring for continuous improvement?
  3. Contingency planning?

Deployment

Task

1. How are models validated?
  - a. Confounding & validity?
  - b. Parameters of reliable use?

Testing

Data

1. What are we trying to do?
2. Definition of success / failure?
  - a. Metrics & comparator
3. Whose interests impacted?
  - a. Benefits / risks / fairness / autonomy
  - b. Strategies to promote / reduce, mitigate

1. Do we have permission / access to data that supports use case?
  - a. Suitable ontology?
  - b. Representative?
  - c. Direct measure of relevant features or use of proxies?
    - i. Are proxies valid?

Model

What policy is the system implementing?

**Procedures & expectations**

**Reporting, coordination & oversight.**