NATIONAL ACADEMIES Sciences Engineering Medicine

# Emerging Hazards in Commercial Aviation – Report 2

## Ensuring Safety During Transformative Changes

# Study Origin

## CONSOLIDATED APPROPRIATIONS ACT of 2021
## SEC. 132. EMERGING SAFETY TRENDS IN AVIATION

*(a) **General** —Not later than 180 days after the date of enactment of this title, the Administrator shall enter into an agreement with the Transportation Research Board for the purpose of developing an annual report identifying, categorizing, and analyzing emerging safety trends in air transportation.*

*(b) **Factors** —The emerging safety trends report should be based on the following data:*

*(1) The NTSB's investigation of accidents under section 1132 of title 49, United States Code 554.*

*(2) The Administrator's Investigations of accidents under section 40113 of title 49, United States Code.*

*(3) Information provided by air operators pursuant to safety management systems.*

*(4) International investigation of accidents and incidents, including reports, data, and information from foreign authorities and ICAO.*

*(5) Other sources deemed appropriate for establishing emerging safety trends in the aviation sector, including the FAA's annual safety culture assessment required under subsection (c)*

# Study Origin (continued)

*(c) **Safety Culture Assessment -** The Administrator shall conduct an annual safety culture assessment through fiscal year 2031, which shall include surveying all employees in the FAA's Aviation Safety organization (AVS) to determine the employees' collective opinion regarding, and to assess the health of, AVS' safety culture and implementation of any voluntary safety reporting program.*

*(d) **Existing Reporting System** – The Executive Director of the Transportation Research Board, in consultation with the Secretary of Transportation and Administrator, may take into account and, as necessary, harmonize data and sources from existing reporting systems within the Department of Transportation and FAA.*

*(e) **Biennial Report To Congress** – One year after the Administrator enters into the agreement with the Transportation Research Board as set forth in subsection (a) and biennially thereafter through fiscal year 2031, the Executive Director, in consultation with the Secretary and Administrator, shall submit to the congressional committees of jurisdiction a report identifying the emerging safety trends in air transportation.*

# Committee Members
# Phase 2

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# Year 2-3 Objectives: Emerging Trends in Aviation Safety and Transformative Changes

*Emerging trends in safety* includes both
(1) new hazards emerging via proposals for new technologies or operations
(2) current concerns that may be evolving to become prominent

***In this report we focus especially on (1), i.e. new hazards with new things***

We focus particularly on *transformative changes*, i.e. things sufficiently novel that their impact on safety and risk cannot be extrapolated from current data and analysis methods

Innovation often involves *new entrants*, i.e., companies without experience in aviation – including aviation's particular methods for safety management and emphasis on safety culture

# From Report 1 - Potential Stressors on Aviation Safety

CLIMATE

Extreme Weather Events, Fuel Alternatives

NEW TECHNOLOGIES

Evolving Technologies, Additive Manufacturing,

NEW ENTRANTS

Drones, Space Travel, Air Taxis, Supersonic Flight

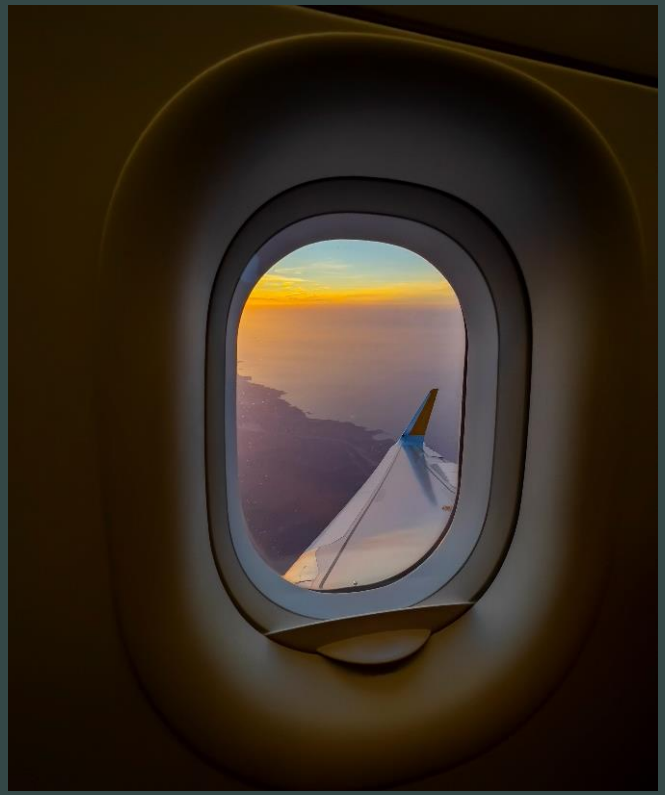
CHANGING BUSINESS MODELS

INCREASINGLY COMPLEX SYSTEMS

# Report Organization Using Safety Management Principles

| | SMS Component | Elements |
|---|---|---|
| Predictive Processes (Chapter 2) | 1. Safety Risk Management | Hazard identification<br>Safety risk assessment and mitigation (Includes certification, operational approval, and definition of operating rules) |
| Data Analytic Processes to Monitor and Improve Safety (Chapter 3) | 2. Safety Assurance | Safety performance monitoring and measurement<br>The management of change<br>Continuous improvement of the SMS |
| Organizational Processes & Culture (Chapter 4) | 3. Safety Policy and Objectives | Management commitment<br>Safety accountability and responsibilities<br>Appointment of key safety personnel<br>Coordination of emergency response planning<br>SMS documentation |
| | 4. Safety Promotion | Training and education<br>Safety communication |
| Integrated Safety Management Across the Lifecycle and Across Organizations (Chapter 5) | | |

# Findings and Recommendations



# Predictive Processes for Safety Risk Management

Some background: The FAA plays 3 vital roles in safety risk management:

1. Certification of individual products, personnel and practices of designers, producers, maintainers and aircraft operators. (managed by the Office of Aviation Safety [AVS])
2. Establishing the collective Operating and Flight Rules and procedures by which aircraft are operated within the National Airspace System (NAS). (managed by AVS and Air Traffic Operations [ATO])
3. Deployment, operation and maintenance of the air traffic management system (new equipment, operations and procedures) that provide aircraft separation, air traffic control and air traffic management. (managed by the ATO)

# Predictive Processes for Safety Risk Management

## More background on certification:

- **Type Certification:** approval of new aircraft, engines, and propellors. Specific standards given for different categories:

  Part 23 for Normal Category Airplanes, Part 25 for Transport Category Airplanes, Part 27 for Normal Category Rotorcraft, Part 29 for Transport Category Rotorcraft, Part 33 for Aircraft Engines, and Part 35 for Propellors.
- **Production Certification**: A certified product has to be produced in an organization that has proved to the FAA that they can faithfully reproduce an airworthy design.
- **Airworthiness Certification**: Ongoing demonstration that specific aircraft meets established standards
- **Operator Certification**: Commercial operator needs to be certified as an organization: Part 91, 135 and 121
- **Personnel Certification**: : Part 61 details certification of pilots, flight instructors and ground instructors, Part 63 details certification of other flight crew members (flight engineers and flight navigators), and Part 65 details certification of "airmen other than flight crew members" including air traffic control operators, dispatchers, mechanics, repairment, and parachute riggers.

# Predictive Processes for Safety Risk Management

Final bit of background on certification: 3 trends noted by the committee

1. Allowable risk varies depending on the type of aircraft and operation.
2. FAA certification is structured around current technologies and operations. With new technologies, these assumptions may not hold true.
3. Certification mostly requires demonstration of compliance using methods and measures that have been developed over years or even decades.

There are often some gaps in the available guidance, which can be covered by “special conditions” as per FAR § 11.19 when FAA finds “that the airworthiness regulations for an aircraft, aircraft engine, or propeller design do not contain adequate or appropriate safety standards, because of a novel or unusual design feature.”

# Predictive Processes for Safety Risk Management

Finding 2-1: Proposals for ***certifying transformative changes pose a unique challenge when current methods of demonstrating compliance do not sensibly describe their characteristics***. Literal adherence to the existing regulations may unnecessarily complicate and delay any attempt at certification or suggest workarounds that do not necessarily support safety. FAA's role should be viewed as ensuring an acceptable level of risk while at the same time providing a reasonable path for innovation within the broad intent of safety risk management.

Recommendation 2-1: ***AVS should evaluate current regulations, guidance, and standards to determine if they limit or preclude certification of transformative changes*** in technologies and commensurate changes in personnel, production, and operating certificates, or appear to disincentivize new features that may enhance safety in different ways than historically assumed. Where such a situation is found, certification processes and standards should be updated to promote effective safety risk management within these new developments, including collaboration with industry where appropriate.

# Predictive Processes for Safety Risk Management

Finding 2-2: For most types of operations, ***the FAA AVS does not currently have mechanisms for comprehensive safety risk management that spans the different organizations*** certifying technologies, personnel, and operating certificates, and governing the general operating and flight rules of the national airspace system (NAS). Since the regulatory offices are organized around how the NAS operates today, transformative changes can be difficult, if not impossible, to address.

Recommendation 2-2: ***FAA should establish crosscutting positions***, staffed by officials responsible for examining proposed transformative changes that simultaneously seek ***to manage safety and risk by purposeful, integrated changes to technologies, personnel, and operating certificates,*** and authorized to identify suitable means of compliance for, and certify, such transformative changes based on their collective mitigation of risk.

# Predictive Processes for Safety Risk Management

Finding 2-3: ***Current standards*** for certification and operational approval for many functions necessary for safe flight prescribe technologies, roles, and skills for personnel, and operating rules that ***assume historic concepts of operations and architectures***. These assumptions do not fit with, and can conflict with, proposed transformative changes to aviation technology and operations. Instead, performance-based standards can direct assessments of how well a proposed technology or operation meets safety standards and do so in a manner directly supporting certification and operational approval.

Recommendation 2-3: ***AVS should lead the definition of performance-based standards*** for flight-critical functions that allow for different equipage, different methods of performing the functions, and a different distribution of who or what is performing the functions' constituent activities, including changes in distribution of activity between human or machine, on the aircraft or on the ground, by the operator (e.g., airline), air traffic or a third party. These performance-based standards should be developed to the point that they can serve as a basis for certification and for approving new operations within the National Airspace System.

# Predictive Processes for Safety Risk Management

Key background on General Operating and Flight Rules:

- Need to work for all stakeholders – (mostly) unlike certification
- Ripple through to many people and their specifications (e.g. pilots, ATC)
- Have evolved into tight structure of VFR & IFR

Finding 2-4: Radical transformations to general operating and flight rules are being proposed, or will be necessary, to safely operate proposed vehicles. However, ***there are no systematic, rigorous, broadly documented methods for identifying, categorizing, and analyzing the risks that may emerge with novel operating and flight rules***, especially where the changes are sufficiently transformative that they cannot be predicted via extrapolations from the present day.

Finding 2-5: Different aircraft operators cannot use conflicting general operating and flight rules in the same airspace, highlighting that these ***flight rules cannot be developed independently by individual applicants, but must have some guiding structure*** and constraints that is fair to all in terms of access to the airspace and safety for all in the airspace while minimizing undue constraints on innovation.

# Predictive Processes for Safety Risk Management

Recommendation 2-4: Congress should ensure that ***fundamental and generalizable research is chartered to establish a systematic and repeatable framework for analyzing and designing civil aviation general operating and flight rules*** that enable novel technologies and operations to share the airspace with current operations. This requires fundamental and generalizable research beyond FAA's current research expertise and portfolio, and may need the support of other agencies conducting fundamental research into operational system-wide safety. These methods must calculate the appropriate performance requirements for all the functions noted earlier, be able to identify and characterize safety concerns created or mitigated by the operating and flight rules, and be detailed enough to articulate the specific activities, and required information needs and control authority, of all actors and stakeholders and how these activities combine to create safe operations.

Recommendation 2-5: ***FAA and the aviation industry develop a process for defining the general operating and flight rules that enable new, innovative operations to coexist in the airspace*** with other innovative operations as well as legacy operations. FAA should launch a single-purpose group (e.g. task force, aviation rule making committee, etc.) including representatives of all relevant stakeholders from legacy and new operations for the purpose of identifying the fundamental structure of and constraints on operating and flight rules for broad classes of current and proposed new operators in the NAS. This should include consensus-based recommendations for development of technical standards that characterize all relevant aspects of the proposed operations relevant to assessing their safety and that identify the essential constraints on and performance measures of new operating rules needed to address potential risks emerging from changes in the operations.

# Safety Assurance – What Data?

Finding 3-1: Proposed transformative changes in technology and operations provide both challenges and opportunities to ***rethink the appropriate data to collect to support safety assurance***. Given that many new technologies can record a wide range of new measures, the opportunity exists to systematically determine what potential data streams best monitor potential safety concerns emerging with innovations. This should particularly consider the unique safety concerns with changing roles of human and machine, and with the unique concerns with monitoring software-intensive functions. This should also capitalize upon criteria used in certification and approval of transformative changes, including monitoring of criteria applied earlier in certification and other safety risk management processes based on performance-based standards and on special criteria and conditions.

Finding 3-2: VSRPs are a vital data source in safety assurance, given the ability of personnel throughout the NAS to detect and describe anomalies. ***Changing roles between human and machines,*** particularly with increasingly automated functions and remotely piloted aircraft, may ***impact human observability of safety concerns***. In such cases, the personnel expected to provide VSRP reports, and the questions they are asked within the report, may need to change. Likewise, further digital data may be required to make up for gaps in, and to make sense of, VSRP reports.

# Safety Assurance – What Data?

Recommendation 3-1: ***AVS should determine the process and criteria by which an applicant can demonstrate that their proposed data set is appropriate for safety assurance when implementing transformative changes in technology and operation***. This determination should be sufficiently proactive to identify where new sensors and recording mechanisms need to be built into systems during their design and certification to then enable safety assurance during their operation. These data sets can leverage the criteria used in safety risk management (including certification and operational approval) to demonstrate safety of their new attributes through performance-based standards and through the special conditions and criteria.

# Safety Assurance – How to Analyze the Data?

Finding 3-3: ***Extensive data analysis methods have been established in other domains*** and industries suitable for expanding the capabilities of aviation safety assurance. These methods particularly span the needs of transformative changes to technologies and operations, where simple definitions of exceedances cannot span the open questions in possible safety concerns that need to be monitored for; instead, ***transformative changes require a range of methods, from those suitable for monitoring for, characterizing, and predicting potential concerns to detecting the unknown.***

Recommendation 3-2: AVS should determine the process and criteria by which an applicant can demonstrate that their proposed ***data analysis methods are appropriate for safety assurance when implementing transformative changes in technology and operation***, and that they are appropriate for the data set being collected. This determination should specifically ***support both (1) characterizing phenomena that are only hypothesized or poorly understood as a result of transformative changes; and (2) monitoring for situations and conditions that are unknown and statistically abnormal, and thus should be flagged for further evaluation.***

# Organizational Processes and Culture – AVS Safety Culture Survey

Finding 4-1: ***The committee supports the AVS shift in 2023 to a survey based on the ten International Atomic Energy Agency (IAEA) safety culture traits*** and its efforts to improve the response rate. The appointment by AVS of a manager with experience in the safety culture assessment process is appropriate. These steps represent good progress, although the committee observes that the congressional request for the annual assessment of the AVS safety culture was enacted in December 2020; while the second survey had been completed at the time of the committee's briefing in March 2024, the overall second annual assessment was incomplete.

Finding 4-2: A safety culture survey represents but the initial step in an ongoing dialogue and discovery process between senior management and employees about the safety culture of an organization and how it can be strengthened. For the committee to carry out its charge of reviewing AVS's annual safety culture assessment ***requires greater insight into the steps being taken by AVS to assess its culture beyond the survey and how it is using what it is learning to strengthen the AVS safety culture.***

# Organizational Processes and Culture – AVS Safety Culture Survey

Finding 4-3: ***Success in strengthening the AVS safety culture depends heavily on the direct, visible, and frequent engagement of senior AVS management with front line employees*** in enabling, enacting, and elaborating the AVS safety culture. These are not responsibilities that can be delegated to the manager responsible for the safety culture survey. At the time of this writing, the committee lacks evidence about such a level of engagement by the highest levels of AVS management in learning from safety culture assessment and implementing actions aimed at strengthening AVS's safety culture.

Finding 4-4: The emerging concept of the safety culture appropriate for a regulator reflects the view of the IAEA that, if regulators expect the organizations that they regulate to have good safety cultures, they have to understand and model safety culture principles and behaviors themselves. To date, there is ***insufficient research in defining, and distinguishing between, the traits and behaviors of the safety cultures of regulators and the safety culture of those they oversee***. The emerging concept of regulatory safety culture is one that AVS can monitor and learn from. Moreover, FAA could support the development of this concept and its assessment through its research budget.

# Organizational Processes and Culture – AVS Safety Culture Survey

Finding 4-5: The safety culture of any large organization does not change quickly. An annual survey is too frequent to pick up shifts in employee perspectives about the organization's safety culture. (The Nuclear Regulatory Commission conducts a survey every 3 to 5 years). The ***ongoing assessment process of the AVS safety culture can also employ appropriate cycles of other processes***, such as focus groups, ongoing dialogue with front-line employees, and input from the employee voluntary reporting system can help AVS articulate and mature its safety culture.

# Organizational Processes and Culture – AVS Safety Culture Survey

Recommendation 4-1: Congress should continue requiring that FAA AVS assess its safety culture, but ***allow AVS the flexibility to reduce the frequency of the safety culture survey, and in alternate years allow AVS to focus more of its annual assessment efforts on formal and informal communication*** by leadership, conduct of focus groups and other forms of dialogue with employees about their perceptions of AVS's safety culture, and feedback to employees about what leadership is learning through the assessment process and the changes it is making in response. Within this process, AVS should identify two or three major goals the organization has in strengthening its safety culture and a short list of actions it will be taking in the next assessment. Likewise, AVS should identify the safety culture traits and behaviors it should model as a regulator to the industry organizations it oversees.

Recommendation 4-2: The safety culture assessment manager that AVS has added to its staff should report regularly to ***the AVS Associate Administrator and the FAA Administrator, both of whom should be responsible for appropriate actions*** to enable a strong, and continuously improving, AVS safety culture.

# Principles and Attributes of Regulator Safety Culture

| Principles | Attributes |
|---|---|
| **1. Leadership for safety is to be demonstrated at all levels in the regulatory body.** | (a) "Safety first" is a guiding principle in the regulatory body.<br>(b) All leaders throughout the regulatory body demonstrate a commitment to safety in their decisions and behaviors.<br>(c) Leaders create an environment for positive development of the safety culture.<br>(d) Leaders clearly define individual roles, responsibilities, and authority.<br>(e) Leaders ensure that the necessary resources are available to meet the safety mission. |
| **2. The culture of the regulatory body promotes safety and facilitates cooperation and open communication.** | (a) Personal commitment to and accountability for safety from every staff member, at all levels of the organization.<br>(b) A strong sense of collaboration and co-ordination of activities across the organization.<br>(c) The need for moral courage and agility in doing the right thing. |
| **3. All staff of the regulatory body have individual responsibility and accountability for exhibiting behaviors that set the standard for safety.** | (a) Openness and transparency.<br>(b) Clear organizational commitment to co-operation.<br>(c) A questioning attitude, and mechanisms to raise differing opinions on regulatory decisions.<br>(d) Promotion of safety and associated knowledge. |
| **4. Implementing a holistic approach to safety is ensured by working in a systematic manner.** | (a) A healthy respect for the consequences of all actions and decisions taken by the regulatory body.<br>(b) Clear awareness of roles and responsibilities in relation to licensees.<br>(c) A clear regulatory framework.<br>(d) Proactivity, adaptability and a holistic approach.<br>(e) Recognition of the complexity of safety issues. |
| **5. Continuous improvement, learning and self-assessment are encouraged at all levels in the organization.** | (a) Looking at ourselves in the mirror: safety culture self-assessment and peer reviews.<br>(b) Learning from experience, fostering exchanges and increasing knowledge.<br>(c) Knowledge management to build a healthy safety culture.<br>(d) Continuous improvement as a clear value of the regulatory body. |

# Organizational Processes and Culture – Oversight of Safety Culture in the Aviation Industry

Finding 4-6: The components of safety management, the data they generate, and their implementation in a safety management system ***(SMS), can provide FAA with a primary mechanism for oversight of organizations' safety culture maturity***, how safety management will be integrated into operations and management by new entrants, and how safety management can be applied throughout the organization for continual improvement.

Finding 4-7: ***Promising safety indicators*** to support both industry organizational structures and safety culture and FAA oversight would include: testing of employee competence in understanding and executing risk controls; feedback between front-line employees and system developers regarding identification and management of hazards; identification and response to unanticipated emerging hazards within the organization; results from employee voluntary reports, SMS audits, audit deficiencies, and corrective action plans and timeliness of response to them; and other indicators of the organizations preoccupation with what might go wrong and continual improvement.

# Integrated Safety Management - Across Organizations

***Prime organizations can outsource parts and labor, but they can't outsource the safety risk these arrangements may bring to their product or operation***

Finding 5-1: ***Safety cannot be regulated by examining only the safety management processes of a prime organization*** that involves third-party suppliers or service providers in support of their design, production or aircraft operation; likewise, it is not sufficient for the regulator to oversee each organization separately. Instead, the prime organization's decision to involve others, including purchasing their products and services, requires a deliberate, layered approach to safety management that ensures all contributions together comply with their safety risk management and safety assurance processes, and are based on appropriate organizational processes and culture. The regulator has the role in overseeing that this layered safety management is implemented and continuously monitored and used to manage safety across all constituent organizations.

Recommendation 5-1: AVS should establish the personnel, mechanisms, and policies ***that enable oversight of effective layered safety management*** of an organization applying for certification, ensuring that this safety management also spans the contributions of those third parties whose products and services contribute to safety. This oversight must ensure that this layered safety management is not only implemented correctly at the time of initial certification but also continuously applied.

# Integrated Safety Management – Across the Lifecycle

Finding 5-2: Often, the entities that seek to certify products, to certify personnel, and to operate and maintain aircraft are separate, uncoordinated organizations, and they may be active at very different points in time. ***Safety is bolstered when each entity, at the time of its activity,*** is expected to capture the data and knowledge that ***informs safety management by those*** reasonably expected to use the same technologies or operations ***after them***.

Recommendation 5-2: ***AVS should identify and characterize the data and knowledge*** associated at each stage in designing, testing, maintaining, and operating aircraft that then can be ***useful to safety management in the life*** of the product or operation. This data and knowledge should be required to be captured at the time, and later integrated into subsequent activities in support of both safety risk management and safety assurance.

# Integrated Safety Management – The FAA's Role…

Unlike the popular conception of FAA as the technical expert who provides final, definitive assessments of a product's or person's safety to fly, aviation is such an immense undertaking in scale, compounded by safety also requiring incredible attention to detail, that FAA cannot be expected to directly oversee all aspects…. Instead, this chapter posits safety management as the process that FAA should ensure is properly occurring longitudinally across the life of products and operations, and also across organizations.

# Integrated Safety Management – Is the FAA Ready?

Finding 5-3: Recent events suggests that AVS may already be challenged to regulate all aspects of the NAS. Transformative changes will further pose challenges with managing new risks. To address ***both current and likely future technologies and operations will require adequate funding and staffing***, and requires this staff has ***requisite technical expertise*** across the full spectrum of technologies. Furthermore, AVS staff must have the ***training and vision to oversee broad safety management processes*** spanning the life of a product (design, production, and operation), spanning multiple organizations, and considering the organization structures and culture needed in these organizations that they oversee.

Recommendation 5-3: ***The FAA AVS should evaluate their personnel requirements*** in light of the demands placed on the workforce in identifying and addressing both existing and emerging risks. Emphasis should be placed on expertise required to oversee and evaluate new and emerging technologies and operations, to oversee the transition from safety risk management to safety assurance as new technologies and operations are implemented, to support the maturation of safety culture within the industry organizations it oversees, and to ensure rigorous safety management processes within all the contributing organizations that impact aviation safety.

# The Last Official Finding – Somethings Gonna Go Wrong…

… Each transformative change represents a step-change in knowledge – and each of these step changes may have gaps in this knowledge that are undetectable and inscrutable until later, with experience. Thus, it is important to constantly understand that, even after the best safety risk management process before implementation, something unexpected may happen once something new takes flight…

Finding 5-4: The aviation industry, and FAA in all its roles, should remain vigilant for emerging safety risks as new technologies and operations are implemented—to detect the precursor before it manifests as an accident, to investigate unexpected behaviors and effects to characterize their safety and risk, and to be open-minded and prepared to seek new mitigations to newly identified risks.

# Overarching Theme – New Concerns Always Emerge

Even when all is properly regulated and evaluated in best faith to the extent suggested by human understanding, any first-time implementation represents a new frontier … in which the unexpected can manifest subtly or suddenly and violently. …the aviation industry, and the FAA in all its roles, should remain vigilant for emerging safety risks as new technologies and operations are implemented – to detect the precursor before it manifests as an accident, to investigate unexpected behaviors and effects to characterize their safety and risk, and to be open-minded and prepared to seek new mitigations to newly identified risks. (F5.4)

***Safety Management is Never Finished***

# In Conclusions – Gaps in the State of the Art

- Gaps that may be more fundamental than the FAA's usual research role:
  - For performance-based standards - conceptual understanding of all the functions that enable safe flight, without assumptions of who (or what) performs the function and where they are situated, how they are performed, and the types of technologies involved.
  - Methods to rigorously and systematically design and assess transformative changes to general operating and flight rules.

- Going beyond aviation alone:
  - "How to continually mature a safety culture?"
    - what is the role of a regulator, such as FAA AVS, in overseeing an industry organization's safety culture, and how do they do so?
    - what metrics are appropriate for an organization, and its regulator, to continually monitor and reflect upon, w.r.t. safety culture?
  - Gaps in the science underlying the highest levels of safety management.
    - managing safety across multiple organizations – with varying types of interaction
    - what does one organization needs to do right now (e.g., build in data collection mechanisms and capture knowledge) for later organizations to safely implement their developments?

- Many of them are sufficiently fundamental that research agencies such as the National Science Foundation, NASA Aeronautics, and DoD research labs may have a role

***The role for FAA AVS may be to create representative test cases and data sets for the broad national research enterprise to examine, in addition to, or instead of, attempting to single-handedly perform this research in-house.***

# The report is now accessible through the National Academies Press (NAP.edu)

https://nap.nationalacademies.org/catalog/27805/emerging-hazards-in-commercial-aviation-report-2-ensuring-rau1safety-during