Ten Domains, Zero Standards

The Autonomous System Certification Gap

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Ten Domains, Zero Standards The Cross-Sector Case for Independent Autonomous System Certification Executive Summary Autonomous systems are being deployed across at least ten safety-critical domains with no standardized mechanism for independent behavioral verification. In aerospace, independent certification prevented a generation of 737 MAX crashes. In autonomous vehicles, healthcare AI, industrial robotics, and seven other domains, that certification infrastructure does not exist—and incidents are accumulating.

The rapid deployment of autonomous systems across transportation, industry, healthcare, infrastructure, defense, and logistics has outpaced the development of safety certification mechanisms.

In each domain, autonomous systems are making consequential decisions—controlling vehicles, administering medications, operating heavy machinery, managing power distribution—without independent verification that these systems operate within their designed parameters.

This paper provides a domain-by-domain analysis of the autonomous system deployment landscape, documenting the specific regulatory gaps, real-world incidents, and institutional failures in each sector.

It demonstrates that the absence of independent behavioral verification is not a single-industry problem but a cross-sectoral structural deficiency that demands a domain-agnostic solution.

ODDC is designed to be that solution. Because it certifies behavioral conformance to a formally specified Operational Design Domain rather than domain-specific technical requirements, ODDC applies across all ten domains without requiring separate certification standards for each sector. The ENVELO Interlock enforces boundaries regardless of whether the system controls a vehicle, a surgical robot, or a power grid. CAT-72 testing verifies behavioral conformance regardless of the domain. One certification architecture. Ten domains. Zero gaps.

1. The Lesson of Aviation

The Boeing 737 MAX disasters illustrate what happens when self-certification replaces independent verification in the most regulated industry on Earth. In October 2018 and March 2019, two crashes killed 346 people. Investigations revealed that the Maneuvering Characteristics Augmentation System (MCAS)—an automated flight control system—activated based on data from a single angle-of-attack sensor and pushed the aircraft nose down repeatedly. Pilots were not adequately informed about MCAS or trained to counteract it.

The critical failure was not technical but institutional. Under the Organization Designation Authorization (ODA) program, Boeing employees acting as FAA designees had certified the safety of the MCAS design. The entity being evaluated was also, effectively, the entity performing the evaluation. A 2020 House Transportation Committee investigation found that Boeing concealed critical information from the FAA, Boeing engineers, and airline customers. The FAA's reliance on manufacturer self-certification failed to catch a design that would have been flagged by truly independent evaluation.

The response was instructive. Congress passed the Aircraft Safety and Certification Reform Act of 2020, strengthening FAA oversight of ODA programs and requiring manufacturer transparency. The lesson: even in the most heavily regulated industry, self-certification is insufficient for safety-critical automated systems. Yet today, autonomous systems in at least ten domains operate with less independent oversight than the pre-MAX aviation regime that Congress determined was inadequate.

If self-certification was insufficient for automated flight control—the most regulated domain in the most regulated industry—it cannot be sufficient for autonomous vehicles, surgical robots, warehouse robotics, or any other safety-critical application where no equivalent certification infrastructure exists.

2. Domain-by-Domain Analysis

2.1 Autonomous Vehicles

Deployment Scale: Waymo operates over 2,500 vehicles across six cities, completing 450,000+ rides per week and accumulating 2 million autonomous miles weekly. Waymo has surpassed 100 million miles of fully autonomous driving. Aurora Innovation launched the first driver-out long-haul autonomous trucking service on Interstate 45 between Dallas and Houston. Tesla announced robotaxi operations in Austin beginning June 2025. Waymo is expanding to Washington, D.C., Philadelphia, Dallas, Houston, San Antonio, Miami, and Orlando.

Regulatory Framework: Fragmented across federal and state jurisdictions. NHTSA's updated Automated Vehicle Framework (April 2025) streamlines incident reporting to five days and expands the AV exemption program but remains voluntary. The bipartisan Autonomous Vehicle Acceleration Act (S. 1798) would modernize Federal Motor Vehicle Safety Standards and preempt state bans on Level 4 trucks. State approaches vary: Kentucky SB 241 raised AV truck insurance from $1M to $5M; California authorized noncompliance notices for driverless vehicles starting 2026; Texas designates the ADS owner as the citeable operator.

Incidents: Florida jury awarded $243 million in Tesla Autopilot fatal accident (2025), finding Tesla 33% liable for overstating safety. Waymo recalled 1,212 robotaxis for collisions with stationary objects (May 2025). Waymo recalled 3,067 robotaxis after 20 documented violations of school bus safety laws in Austin and Atlanta (December 2025). Cruise robotaxi dragged pedestrian 20 feet; operations suspended and ~1,000 vehicles recalled (2023). NHTSA data: 400 crashes involving automated driving systems in one reporting year; Tesla ADAS vehicles accounted for 53.9% of incidents.

Gap: No independent mechanism verifies that an autonomous vehicle's Operational Design Domain is correctly specified, that the vehicle actually operates within that ODD, or that software updates maintain conformance. NHTSA's enforcement is reactive—recalls occur after failures, not before. The Waymo school bus incidents demonstrate that even the industry's most tested system can systematically violate safety rules without any independent monitoring system detecting it.

2.2 Industrial Robotics

Deployment Scale: The International Federation of Robotics reports over 4 million operational industrial robots globally as of 2024, with approximately 541,000 new installations annually. The automotive, electronics, and logistics sectors are the largest deployers. Amazon operates over 750,000 robotic units across its fulfillment network. Tesla's Giga Texas and Giga Berlin facilities use extensive Fanuc and KUKA robotic installations.

Regulatory Framework: OSHA's General Duty Clause (Section 5(a)(1)) is the primary federal mechanism. Industry standards include ISO 10218 (robot safety), ISO/TS 15066 (collaborative robots), ISO 12100 (risk assessment), and ANSI/RIA R15.06 (integration). These standards govern design and integration processes but do not include continuous behavioral monitoring or independent conformance verification during operation.

Incidents: Tesla-Fanuc $51 million lawsuit after robotic arm struck worker with ~8,000 pounds of force at Giga Texas (September 2025). OSHA data: 77 robot-related workplace accidents from 2015–2022 producing 93 injuries including amputations, fractures, and crushing injuries.

NIOSH: 61 robot-related fatalities 1992–2015. Korean occupational safety data: 369 robot-related accidents in a single decade (27–49/year) despite mandatory risk assessments. Amazon warehouse injury rates in robotic facilities up to 50% higher than non-robotic facilities. OSHA reached its largest-ever corporate-wide settlement with Amazon in December 2024 over hazardous working conditions across 10 facilities. The U.S. Attorney's Office for the Southern District of New York is separately investigating whether Amazon conspired to conceal workplace injuries.

Gap: ISO standards govern design and integration but not runtime behavior. No independent mechanism verifies that a robot operates within its programmed safety parameters during actual operation. The Tesla-Fanuc case alleges the robot operated outside its programmed parameters—the kind of behavioral deviation that continuous conformance monitoring would detect.

2.3 Healthcare AI

Deployment Scale: The FDA has authorized over 950 AI/ML-enabled medical devices as of 2024, spanning radiology, cardiology, pathology, and clinical decision support. Surgical robotics (Intuitive Surgical's da Vinci, Medtronic's Hugo) perform over 1.5 million procedures annually worldwide. AI-powered clinical decision support systems are deployed in thousands of hospitals for drug interaction checking, sepsis prediction, and diagnostic assistance.

Regulatory Framework: The FDA regulates AI medical devices through its Software as a Medical Device (SaMD) framework and Total Product Lifecycle approach. Pre-market review evaluates algorithm performance on test datasets. Post-market surveillance depends on manufacturer adverse event reporting (MDR). The FDA's proposed framework for predetermined change control plans would allow iterative AI updates without full re-review—but the behavioral verification mechanism is unclear.

Incidents: ECRI ranked AI systems deployed without proper oversight as the #1 health technology hazard for 2025. ECRI's patient safety report ranked insufficient AI governance as the #2 threat. The Department of Justice subpoenaed pharmaceutical and digital health companies over AI deployed in electronic medical record systems (2024). A 2024 academic analysis identified 51 court cases involving software-related patient injuries from drug management, clinical decision support, and surgical robotics. Stanford HAI found that no well-articulated testing process exists for healthcare AI and tools are tested only by their developers.

Gap: Pre-market testing evaluates performance on curated datasets; it does not verify that the AI system's behavior remains within specification under real-world clinical conditions.

Post-market surveillance depends on manufacturer self-reporting. No independent mechanism continuously verifies that a clinical decision support system's recommendations remain within safe parameters.

2.4 Data Centers and Cloud Infrastructure

Deployment Scale: Hyperscale data centers are increasingly reliant on autonomous systems for cooling management, power distribution, and workload orchestration. AI workloads are driving rack densities from 30–50 kW per rack today to projected 250 kW per rack by 2030. Global data center power consumption is projected to exceed 1,000 TWh by 2028. Companies are deploying AI-powered systems to manage thermal loads, predict equipment failures, and optimize energy distribution without human intervention.

Regulatory Framework: No specific regulatory framework governs autonomous decision-making in data center operations. Uptime Institute Tier classifications address redundancy design but not autonomous system behavior. SOC 2 audits verify infrastructure controls but not the behavior of AI systems managing that infrastructure.

Incidents: CyrusOne's Aurora, Illinois facility experienced a cooling system failure in 2025 that disrupted CME Group's derivatives trading platform. AWS US-EAST-1 suffered a major outage in October 2025 with cascading effects across dependent services. Cloudflare experienced two separate incidents in November and December 2025 affecting routing and DNS resolution. Each incident involved autonomous management systems making decisions that amplified rather than contained failures.

Gap: No independent mechanism verifies that autonomous cooling, power, and workload management systems operate within safe parameters. When an AI system managing rack cooling makes a decision that leads to thermal runaway, no independent conformance record establishes whether the system was operating within its design envelope. The increasing density of AI workloads amplifies the consequences of autonomous management failures.

2.5 Energy Grid

Deployment Scale: Autonomous systems are increasingly managing grid balancing, renewable integration, and demand response across national power networks. Data centers consumed 20% of Ireland's total electricity in 2024, prompting a halt on new data center builds in Dublin.

The average age of large power transformers in the U.S. exceeds 40 years. AI systems are being deployed to manage the complex interaction between aging infrastructure and rapidly growing AI-driven demand.

Regulatory Framework: FERC and NERC govern grid reliability, with Critical Infrastructure Protection (CIP) standards addressing cybersecurity for bulk power systems. However, these standards address grid operator procedures, not the behavior of AI systems making autonomous grid management decisions. No framework verifies that an AI system managing load balancing will not make decisions that destabilize the grid during peak demand.

Gap: The combination of AI-driven demand growth, aging infrastructure, and autonomous grid management creates a scenario where the systems consuming the most power are also the systems managing the infrastructure delivering it. No independent mechanism verifies that these autonomous management systems operate within safe parameters for grid stability.

2.6 Aviation and Drones

Deployment Scale: The FAA's Part 107 governs small UAS operations. Beyond Visual Line of Sight (BVLOS) operations are expanding rapidly, with Congress mandating Part 108 rulemaking for routine BVLOS operations by January 2026. Zipline's P2 tether-and-droid system completed its first U.S. customer flight in January 2025, targeting one million deliveries per day by 2027.

Walmart completed over 150,000 drone deliveries through 2025. Wing (Alphabet) conducts daily commercial deliveries in multiple U.S. markets.

Regulatory Framework: The FAA maintains the most developed certification framework for autonomous systems through its airworthiness certification process, type certificates, and operational approvals. Part 108 BVLOS rules will codify detect-and-avoid requirements, remote-pilot licensing, and air-risk tiers. However, the drone delivery segment is rapidly outpacing regulatory capacity—hundreds of thousands of autonomous flights are occurring under waivers and exemptions rather than standardized certification.

Gap: While the FAA's framework is the most mature for autonomous systems, the explosive growth of drone delivery operations is creating certification backlogs. BVLOS waivers grant operational permission without the kind of continuous behavioral verification that traditional aviation certification requires. As delivery drones scale to millions of daily operations, the gap between waiver-based approval and continuous conformance monitoring becomes a systemic risk.

2.7 Defense and Military

Deployment Scale: The Department of Defense's Replicator initiative aims to deploy autonomous systems at scale. Autonomous surveillance, reconnaissance, logistics, and weapons systems are in various stages of development and deployment. The Ukraine conflict has accelerated the operational use of autonomous drones and AI-assisted targeting systems.

Regulatory Framework: DoD Directive 3000.09 governs autonomous and semi-autonomous weapon systems, requiring appropriate levels of human judgment. The DoD's Responsible AI Strategy and Ethical Principles for AI provide governance guidance. NATO's AI Strategy addresses interoperability requirements. However, operational testing and evaluation for autonomous defense systems lacks standardized behavioral verification procedures comparable to traditional weapons system testing.

Gap: The speed of autonomous defense system deployment, particularly in the context of peer adversary competition, creates pressure to deploy before comprehensive behavioral verification is complete. The consequences of autonomous system failures in defense—civilian casualties from incorrect targeting, collateral damage from boundary exceedance, escalation from autonomous system misidentification—are measured not just in liability but in international law and strategic stability.

2.8 Construction and Mining

Deployment Scale: Autonomous haul trucks (Caterpillar, Komatsu) operate in mining operations globally. Caterpillar's autonomous fleet has hauled over 5 billion metric tons since 2013. Built Robotics deploys autonomous excavators and dozers on construction sites. Autonomous concrete pourers, rebar tiers, and site inspection drones are in increasing use.

Regulatory Framework: MSHA (Mine Safety and Health Administration) governs mining operations. OSHA governs construction. Neither agency has specific standards for autonomous heavy equipment. Operational safety depends on manufacturer-specified geofencing and speed limits that are not independently verified during operation.

Gap: Autonomous haul trucks operating in open-pit mines share operational space with human workers and conventional vehicles. The geofencing that constrains these vehicles' operational areas is configured by the operator and not independently verified. When an autonomous haul truck exceeds its operational boundary, the consequences involve hundreds of tons of moving equipment.

2.9 Logistics and Warehousing

Deployment Scale: Amazon operates over 750,000 robotic units across its fulfillment network.

Walmart has completed over 150,000 drone deliveries. Autonomous mobile robots (AMRs) from companies including Locus Robotics, 6 River Systems, and Fetch Robotics operate in thousands of warehouses. The warehouse robotics market is growing at over 14% annually.

Regulatory Framework: OSHA's General Duty Clause is the primary mechanism. No specific federal standard addresses autonomous mobile robot safety in warehouse environments.

Industry standards (ANSI/RIA R15.08 for mobile robots) exist but are voluntary and focus on design rather than operational behavior.

Incidents: Amazon's warehouse injury rate in robotic facilities has been documented as nearly double the non-Amazon warehouse average—up to 5.9 serious injuries per 100 workers in 2020 versus 2.5 at Walmart warehouses. A Strategic Organizing Center analysis found Amazon's 2024 total injury rate was 80% higher than its own 2025 target. The U.S. Senate HELP Committee's 18-month investigation found Amazon workers suffered injuries at 2.6 times the industry rate. OSHA's December 2024 corporate-wide settlement with Amazon—the largest multi-site investigation in over a decade—required ergonomic reforms across all facilities. The Southern District of New York is investigating whether Amazon concealed injury data.

Gap: Warehouse AMRs share space with human workers in dynamic, high-speed environments.

No independent mechanism verifies that these robots maintain safe operational parameters—speed limits, proximity thresholds, load stability—during actual operations. The Amazon injury data suggests that the interaction between autonomous systems and human workers is producing systematic harm that existing standards do not prevent.

2.10 Oil and Gas

Deployment Scale: Autonomous inspection drones survey pipelines and offshore platforms.

AI-powered systems manage drilling operations, detecting anomalies and adjusting parameters without human intervention. Autonomous underwater vehicles (AUVs) conduct subsea inspections and maintenance. Digital twin systems use AI to monitor and predict equipment failures across refineries and processing plants.

Regulatory Framework: BSEE (Bureau of Safety and Environmental Enforcement) governs offshore operations. PHMSA (Pipeline and Hazardous Materials Safety Administration) governs pipelines. API standards address equipment specifications. None of these frameworks include specific requirements for autonomous decision-making systems, AI-powered drilling optimization, or autonomous inspection drones. Environmental and safety

consequences of autonomous system failures in this sector—well blowouts, pipeline ruptures, offshore platform incidents—can be catastrophic.

Gap: When an AI system managing drilling parameters makes an autonomous decision that contributes to a well control incident, no independent conformance record establishes whether the system was operating within its design specifications. The Deepwater Horizon disaster demonstrated the consequences of inadequate independent safety verification in offshore operations. Autonomous systems in this domain inherit those stakes.

3. The Cross-Domain Pattern

The domain-by-domain analysis reveals a consistent pattern across all ten sectors:

Domain	Autonomous Systems	Current Oversight	Independent Behavioral Verification
Autonomous Vehicles	AVs, ADAS, autonomous trucks	NHTSA voluntary framework + state patchwork	None
Industrial Robotics	Industrial robots, cobots	OSHA General Duty + ISO design standards	None
Healthcare AI	Diagnostics, CDS, surgical robots	FDA SaMD + post-market MDR	None
Data Centers	Autonomous cooling, power, workload	SOC 2 + Uptime Tier	None
Energy Grid	Load balancing, demand response	FERC/NERC CIP	None
Aviation/Drones	Delivery drones, BVLOS operations	FAA Part 107/108	Partial (type cert)
Defense	Autonomous ISR, targeting, logistics	DoD 3000.09 + service policies	None
Construction/Mining	Autonomous haul trucks, excavators	MSHA/OSHA + manufacturer specs	None
Logistics	Warehouse AMRs, delivery drones	OSHA General Duty + voluntary ANSI	None
Oil & Gas	Drilling AI, inspection drones, AUVs	BSEE/PHMSA + API standards	None

Of ten domains deploying autonomous systems in safety-critical applications, nine have no independent behavioral verification whatsoever. The tenth—aviation—has partial verification through FAA type certification but is rapidly scaling beyond that framework's capacity as drone operations proliferate. The pattern is unambiguous: autonomous systems are being deployed at scale across every major industry sector without the independent certification

infrastructure that the 737 MAX disasters demonstrated is necessary.

4. Why ODDC Is Domain-Agnostic by Design

The temptation in addressing a cross-domain problem is to propose domain-specific solutions: a certification standard for autonomous vehicles, a separate standard for healthcare AI, a separate standard for industrial robotics. This approach would take decades and produce an inconsistent patchwork of sector-specific requirements—exactly the regulatory fragmentation that already exists.

ODDC takes a fundamentally different approach. It certifies behavioral conformance to a formally specified Operational Design Domain—regardless of what that domain contains. The certification framework asks three universal questions that apply to every autonomous system in every domain:

First: Is the system's Operational Design Domain formally specified? Whether the ODD describes road conditions for an autonomous vehicle, temperature and load parameters for a data center cooling system, or patient population parameters for a clinical decision support tool, the specification is formal, machine-readable, and independently verifiable.

Second: Is the system's behavior enforced within that ODD? Whether the ENVELO Interlock prevents a vehicle from operating on unmapped roads, prevents a robot from exceeding force limits, or prevents an AI system from making recommendations outside its validated scope, the enforcement mechanism is non-bypassable and independently verified.

Third: Does the system maintain conformance under sustained operation? Whether CAT-72 testing subjects an autonomous truck to 72 hours of continuous highway operation, a warehouse robot to 72 hours of continuous picking cycles, or a clinical AI to 72 hours of continuous recommendation generation, the testing protocol verifies sustained behavioral conformance with tamper-evident results.

This domain-agnostic architecture means that ODDC can be deployed in any sector without waiting for sector-specific standards development. A hospital can use ODDC to verify that its clinical decision support system operates within its validated parameters. A logistics company can use ODDC to verify that its warehouse robots maintain safe operational boundaries. A fleet operator can use ODDC to verify that its autonomous trucks operate within their declared ODDs. One certification framework.

Universal application.

5. The Regulatory Opportunity

The cross-domain nature of the autonomous system certification gap creates a unique regulatory opportunity. Rather than developing separate certification frameworks for each sector—a process that would take a decade or more—policymakers can adopt a single, domain-agnostic certification infrastructure that addresses the behavioral verification gap across all ten domains simultaneously.

5.1 Congressional Action

For Congressional committees, ODDC provides a reference architecture for autonomous system certification that transcends jurisdictional boundaries. The Commerce Committee (autonomous vehicles), Armed Services Committee (defense), Energy and Commerce Committee (healthcare AI, energy grid), and Transportation Committee (drones, autonomous trucks) all face the same structural problem: autonomous systems in their jurisdictions lack independent behavioral verification. ODDC provides a common solution that can be referenced in legislation, guidance, or oversight without requiring each committee to develop sector-specific certification standards.

5.2 Agency Reference

Federal agencies can incorporate ODDC conformance into existing regulatory frameworks without new rulemaking. NHTSA can reference ODDC in its Automated Vehicle Framework guidance. FDA can reference ODDC in SaMD post-market surveillance requirements. OSHA can reference ODDC in enforcement guidance for workplaces deploying autonomous systems. MSHA can reference ODDC for autonomous mining equipment. Each reference leverages an existing enforcement infrastructure rather than requiring agencies to build new certification capacity.

5.3 International Alignment

The EU AI Act's conformity assessment requirements apply across all high-risk domains, including transportation, critical infrastructure, and healthcare. ODDC's domain-agnostic architecture aligns naturally with this cross-sectoral approach. For companies operating in both U.S. and EU markets, a single ODDC certification can support regulatory compliance across both jurisdictions—reducing the compliance burden while raising the safety standard.

6. Conclusion

The autonomous systems revolution is happening faster than the safety certification infrastructure can adapt. Across ten domains, systems are making consequential decisions—controlling vehicles that share roads with children, operating robots that share workspaces with humans, making medical recommendations that affect patient lives, managing power grids that serve millions, and conducting military operations that carry international legal consequences.

In every domain, the same structural deficiency exists: no independent mechanism verifies that these systems operate within their designed parameters. The aviation industry learned this lesson at the cost of 346 lives. The question for every other sector is whether they will learn it preemptively or reactively.

The 737 MAX taught the world that self-certification is insufficient for automated safety-critical systems—even in the most regulated industry on Earth. Today, autonomous systems in ten other domains operate with less independent oversight than the pre-MAX regime that Congress found inadequate. ODDC provides a single, deployable, domain-agnostic certification infrastructure that closes this gap across every sector simultaneously. The standard exists. The need is documented.

What remains is the institutional will to act. REFERENCES [1] U.S. House Transportation and Infrastructure Committee. "Final Committee Report on the Design, Development, and Certification of the Boeing 737 MAX." September 2020. [2] Aircraft Safety and Certification Reform Act of 2020. Pub. L. 116-260, Division V. [3] Florida Jury Verdict, Tesla Autopilot Fatal Accident. $243 million award, 33% manufacturer liability. 2025. [4] Waymo Recall of 1,212 Robotaxis. NHTSA investigation—collisions with stationary objects. May 2025. [5] Waymo Recall of 3,067

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This document references publicly available government reports, court filings, regulatory publications, and peer-reviewed research. This document does not constitute legal advice.