Questions on the Proposed Revision of the EMS Agenda

Responses to the following questions are requested to help plan the revision of the EMS Agenda. Please provide references as appropriate.

1. What are the most critical issues facing EMS systems that should be addressed in the revision of the EMS Agenda? Please be as specific as possible.

2. What progress has been made in implementing the EMS Agenda since its publication in 1996?

3. How have you used the EMS Agenda? Please provide specific examples.

4. As an EMS stakeholder, how might the revised EMS Agenda be most useful to you?

5. What significant changes have occurred in EMS systems at the national, State and local levels since 1996?

6. What significant changes will impact EMS systems over the next 30 years?

7. How might the revised EMS Agenda support the following FICEMS Strategic Plan goals:
   a. Coordinated, regionalized, and accountable EMS and 9–1–1 systems that provide safe, high-quality care;
   b. data-driven and evidence-based EMS systems that promote improved patient care quality;
   c. EMS systems fully integrated into State, territorial, local, tribal, regional, and Federal preparedness planning, response, and recovery;
   d. EMS systems that are sustainable, forward looking, and integrated with the evolving health care system;
   e. an EMS culture in which safety considerations for patients, providers, and the community permeate the full spectrum of activities; and
   f. a well-educated and uniformly credentialed EMS workforce.

8. How could the revised EMS Agenda contribute to enhanced emergency medical services for children?

9. How could the revised EMS Agenda address the future of EMS data collection and information sharing?

10. How could the revised EMS Agenda support data-driven and evidence-based improvements in EMS systems?

11. How could the revised EMS Agenda enhance collaboration among EMS systems, health care providers, hospitals, public safety answering points, public health, insurers, palliative care and others?

12. How will innovative patient care delivery and finance models impact EMS systems over the next 30 years?

13. How could the revised EMS Agenda promote community preparedness and resilience?

14. How could the revised EMS Agenda contribute to improved coordination for mass casualty incident preparedness and response?

15. How could the revised EMS Agenda enhance the exchange of evidence based practices between military and civilian medicine?

16. How could the revised EMS Agenda support the seamless and unimpeded transfer of military EMS personnel to roles as civilian EMS providers?

17. How could the revised EMS Agenda support interstate credentialing of EMS personnel?

18. How could the revised EMS Agenda support improved patient outcomes in rural and frontier communities?

19. How could the revised EMS Agenda contribute to improved EMS education systems at the local, State, and national levels?

20. How could the revised EMS Agenda lead to improved EMS systems in tribal communities?

21. How could the revised EMS Agenda promote a culture of safety among EMS personnel, agencies and organizations?

22. Are there additional EMS attributes that should be included in the revised EMS Agenda? If so, please provide an explanation for why these additional EMS attributes should be included.

23. Are there EMS attributes in the EMS Agenda that should be eliminated from the revised edition? If so, please provide an explanation for why these EMS attributes should be eliminated.

24. What are your suggestions for the process that should be used in revising the EMS Agenda?

25. What specific agencies/organizations/entities are essential to involve, in a revision of the EMS Agenda?

26. Do you have any additional comments regarding the revision of the EMS Agenda?

Issued on: March 22, 2016.

Jeffrey P. Michael, Associate Administrator, Research and Program Development.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0040]

Request for Public Comments on NHTSA Enforcement Guidance Bulletin 2016–02: Safety-Related Defects and Emerging Automotive Technologies

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comments.

SUMMARY: Automotive technology is at a moment of rapid change and may evolve farther in the next decade than in the previous 45–plus year history of the Agency. As the world moves toward autonomous vehicles and innovative mobility solutions, NHTSA is interested in facilitating the rapid advance of technologies that will promote safety. NHTSA is commanded by Congress to protect the safety of the driving public against unreasonable risks of harm that may occur because of the design, construction, or performance of a motor vehicle or motor vehicle equipment, and mitigate risks of harm, including risks that may be emerging or contingent. As NHTSA always has done when evaluating new technologies and solutions, we will be guided by our statutory mission, the laws we are obligated to enforce, and the benefits of the emerging technologies appearing on America’s roadways.

NHTSA has broad enforcement authority, under existing statutes and regulations, to address existing and emerging automotive technologies. This proposed Enforcement Guidance Bulletin sets forth NHTSA’s current views on emerging automotive technologies—including its view that when vulnerabilities of such technology or equipment pose an unreasonable risk to safety, those vulnerabilities constitute a safety-related defect—and suggests guiding principles and best practices for motor vehicle and equipment manufacturers in this context. This notice solicits comments from the public, motor vehicle and equipment manufacturers, and other interested stakeholders on the proposal, as well as additional information and examples of safety-related defects as defined in this guidance.

BILLING CODE 4910–59–P
I. Executive Summary

Recent and continuing advances in automotive technology have great potential to generate significant safety benefits. Today’s motor vehicles are increasingly equipped with electronics, sensors, and computing power that enable the deployment of safety technologies and functions, such as forward-collision warning, automatic-emergency braking, and lane keeping assist, which dramatically enhance safety. New technologies may not only prevent drivers from crashing, but may even do some or all of the driving for them. The safety implications of such emerging technologies are vast. Importantly, as these technologies become more widespread, manufacturers must ensure their safe development and implementation.

To facilitate automotive safety innovation, to aid in the successful development and deployment of emerging automotive technologies, and to protect the public from potential flaws or threats associated with emerging automotive technologies, NHTSA is publishing, for guidance and informational purposes, this Enforcement Guidance Bulletin setting forth the Agency’s current view of its enforcement authority and principles guiding its exercise of that authority. This includes guiding principles and best practices for use by motor vehicle and equipment manufacturers. NHTSA is not establishing a binding set of rules, nor is the Agency suggesting that one particular set of practices applies in all situations. The Agency recognizes that best practices vary depending on circumstances, and manufacturers remain free to choose the solution that best fits their needs and the demands of automotive safety. However, to address safety concerns associated with emerging technologies in a comprehensive way, and to advise regulated entities of the Agency’s present views of certain enforcement subjects and issues, NHTSA submits this proposed Enforcement Guidance Bulletin for public comment. Based on the Agency’s review and analysis of that input, it will develop and issue a final “Enforcement Guidance Bulletin” on this topic.

II. Legal and Policy Background

A. NHTSA’s Enforcement Authority Under the Safety Act

The National Traffic and Motor Vehicle Safety Act, as amended (“Safety Act”), 49 U.S.C. 30101 et seq., provides the basis and framework for NHTSA’s enforcement authority over motor vehicle and motor vehicle equipment defects and noncompliances with federal motor vehicle safety standards (FMVSS). This authority includes investigations, administrative proceedings, civil penalties, and civil enforcement actions. While automation and other advanced technologies may modify motor vehicle and equipment design, NHTSA’s statutory enforcement authority is general and flexible, which allows it to keep pace with innovation. The Agency has the authority to respond to a safety problem posed by new technologies in the same manner it has responded to safety problems posed by more established automotive technology and equipment, such as carburetors, the powertrain, vehicle control systems, and forward collision warning systems—by determining the existence of a defect that poses an unreasonable risk to motor vehicle safety and ordering the manufacturer to conduct a recall. See 49 U.S.C. 30118(b).

This enforcement authority applies notwithstanding the presence or absence of an FMVSS for any particular type of advanced technology. See, e.g., United States v. Chrysler Corp., 158 F.3d 1350, 1351 (D.C. Cir. 1998) (NHTSA “may seek the recall of a motor vehicle either when a vehicle has ‘a defect related to motor vehicle safety’ or when a vehicle ‘does not comply with an applicable motor vehicle safety standard.’”).

Under the Safety Act, NHTSA has authority over motor vehicles, equipment included in or on a motor vehicle at the time of delivery to the first purchaser (i.e., original equipment), and motor vehicle replacement equipment. See 49 U.S.C. 30102(a)–(b). Motor vehicle equipment is broadly defined to include “any system, part, or component of a motor vehicle as originally manufactured” and “any similar part or component manufactured or sold for replacement or improvement of a system, part, or component.” 49 U.S.C. 30102(a)(7)(A)–(B).

The Safety Act also gives NHTSA jurisdiction over after-market improvements, accessories, or additions to motor vehicles. See 49 U.S.C. 30102(a)(7)(B). All devices “manufactured, sold, delivered, or offered to be sold for use on public streets, roads, and highways with the apparent purpose of safeguarding users of motor vehicles against risk of accident, injury, or death” are similarly subject to NHTSA’s enforcement authority. 49 U.S.C. 30102(a)(7)(C).

1 A manufacturer’s obligation to recall motor vehicles and motor vehicle equipment determined to have a safety-related defect is separate and distinct from its obligation to recall motor vehicles and motor vehicle equipment that fail to comply with an applicable FMVSS. See 49 U.S.C. 30120.
With respect to new and emerging technologies, NHTSA considers automated vehicle technologies, systems, and equipment to be motor vehicle equipment, whether they are offered to the public as part of a new motor vehicle (as original equipment) or as an after-market replacement(s) of or improvement(s) to original equipment. NHTSA also considers software (including, but not necessarily limited to, the programs, instructions, code, and data used to operate computers and related devices), and after-market software updates, to be motor vehicle equipment within the meaning of the Safety Act. Software that enables devices not located in or on the motor vehicle to connect to the motor vehicle or its systems could, in some circumstances, also be considered motor vehicle equipment. Accordingly, a manufacturer of new and emerging vehicle technologies and equipment, whether it is the supplier of the equipment or the manufacturer of a motor vehicle on which the equipment is installed, has an obligation to notify NHTSA of any and all safety-related defects. See 49 CFR part 573. Any manufacturer or supplier that fails to do so may be subject to civil penalties. See 49 U.S.C. 30165(a).

NHTSA is charged with reducing deaths, injuries, and economic losses resulting from motor vehicle crashes. See 49 U.S.C. 30101. Part of that mandate includes ensuring that motor vehicles and motor vehicle equipment, including new technologies, perform in ways that “protect[] the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident.” 49 U.S.C. 30102(a)(2). This responsibility also includes the nonoperational safety of a motor vehicle. Id. In pursuit of these safety objectives, and in the absence of adequate action by the manufacturer, NHTSA is authorized to determine that a motor vehicle or motor vehicle equipment is defective and that the defect poses an unreasonable risk to safety. See 49 U.S.C. 30118(b) and (c)(1).

B. Determining the Existence of a Defect

Under the Safety Act, a “defect” includes “any defect in performance, construction, a component, or material of a motor vehicle or motor vehicle equipment.” 49 U.S.C. 30102(a)(2). It also includes a defect in design. See United States v. General Motors Corp., 518 F.2d 420, 436 (D.C. Cir. 1975) (“‘Wheels’ is not a word in an item of motor vehicle equipment (including hardware, software and other electronic systems) may be considered a defect of the motor vehicle itself. See 49 U.S.C. 30102(b)(1)(F).

Congress intended the Safety Act to represent a “commonsense” approach to safety and courts have followed that approach in determining what constitutes a “defect.” Wheels, 518 F.2d at 436. Accord Center for Auto Safety, Inc. v. National Highway Traffic Safety Administration, 342 F. Supp. 2d 1, 15 (D.D.C. 2004); Clarke v. TRW, Inc., 921 F. Supp. 927, 934 (N.D.N.Y. 1996). For this reason, a defect determination does not require an engineering explanation or root cause, but instead “may be based exclusively on the performance record of the component.” Wheels, 518 F.2d at 432 (“A determination of a ‘defect’ does not require any predicate of a finding identifying engineering, metallurgical, or manufacturing failures.”). Thus, a motor vehicle or item of equipment contains a defect if it is subject to a significant number of failures in normal operation, “including those failures occurring during ‘specified use’ or resulting from predictable abuse, but not including those resulting from normal deterioration due to age and wear.” 2 Center for Auto Safety, 342 F.2d at 13–14 (citing Wheels, 518 F.2d at 427).

A “significant number of failures” is merely a “non-de minimus” quantity; it need not be a “substantial percentage of the total.” Wheels, 518 F.2d at 438 n.84. Whether there have been a “significant number of failures” is a fact-specific inquiry that includes considerations such as: The failure rate of the component in question; the failure rate of comparable components; and the importance of the component to the safe operation of the vehicle. Id. at 427. In addition, where appropriate, the determination of the existence of a defect may depend upon the failure rate in the affected class of vehicles compared to that of other peer vehicles. See United States v. Gen. Motors Corp., 841 F.2d 400, 412 (D.C. Cir.1988) (“X-Cars”). Finally, to constitute a defect, the failures must be attributable to the motor vehicle or equipment itself, rather than the driver or the road conditions. See id.

It must be noted, however, that in some circumstances, a crash, injury, or death need not occur in order for a vulnerability or safety risk to be considered a defect. The Agency relies on the performance record of a vehicle or component in making a defect determination where the engineering or root cause is unknown. See Wheels, 518 F.2d at 432. Where, however, the engineering or root cause is known, the Agency need not proceed with analyzing the performance record. See id.; see also United States v. Gen. Motors Corp., 565 F.2d 754, 758 (D.C. Cir. 1977) (“Carburetors”) (finding a defect to be safety-related if it “results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards . . . , can definitely be expected to occur in the future.”). For software or other electronic systems, for example, when the engineering or root cause of the vulnerability or risk is known, a defect exists regardless of whether there have been any actual failures.

C. Determining an Unreasonable Risk to Safety

In order to support a recall, a defect must be related to motor vehicle safety. United States v. General Motors Corp., 561 F.2d 923, 928–29 (D.C. Cir. 1977) (“Pitman Arms”). In the context of the Safety Act, “motor vehicle safety” refers to an “unreasonable risk of accidents” and an “unreasonable risk of death or injury in an accident.” 49 U.S.C. 30102(a)(8). Thus, while the defect analysis has generally entailed a retrospective look at how many failures have occurred (see Wheels, Center for Auto Safety, and Pitman Arms), the safety-relatedness question is forward-looking, and concerns the hazards that may arise in the future. See, e.g., Carburetors, 561 F.2d at 758.

In general, for a defect to present an “unreasonable risk,” there must be a likelihood that it will cause or be associated with a “non-negligible” number of crashes, injuries, or deaths in the future. See, e.g., Carburetors, 565 F.2d at 759. This prediction of future hazards is called a “risk analysis.” See, e.g., Pitman Arms, 561 F.2d at 924 (Leventhal, J., dissenting) (“GM presented a ‘risk analysis’ which predicts the likely number of future injuries or deaths to be expected in the remaining service life of the affected models”). A forward-looking risk analysis is compelled by the purpose of the Safety Act, which “is not to protect individuals from the risks associated with defective vehicles only after serious injuries have already occurred; it is to prevent serious injuries stemming from established defects before they occur.” Carburetors, 565 F.2d at 759 (emphasis added).

2 “The protection afforded by the [Safety] Act was not limited to careful drivers who fastidiously observed speed limits and conscientiously complied with manufacturer’s instructions on vehicle maintenance and operation . . . [the statute provides] an added area of safety to an owner who is lackadaisical, who neglects regular maintenance . . . ” Wheels, 518 F.2d at 434.
If the hazard is sufficiently serious, and at least some harm, however small, is expected to occur in the future, the risk may be deemed unreasonable. Carburetors, 565 F.2d at 759 (“In the context of this case . . . even an ‘exceedingly small’ number of injuries from this admittedly defective and clearly dangerous carburetor appears to us ‘unreasonably large.’”). In other words, where a defect presents a “clearly” or “potentially dangerous” hazard, and where “at least some such hazards”—even an “exceedingly small” number—will occur in the future, that defect is necessarily safety-related. See Carburetors, 565 F.2d 754. This is so regardless of whether any injuries have already occurred, or whether the projected number of failures/injuries in the future is trending down. See id. at 759. Moreover, a defect may be considered “per se” safety-related if it causes the failure of a critical component; causes a vehicle fire; causes a loss of vehicle control; or suddenly moves the driver away from steering, accelerator, and brake controls—regardless of how many injuries or accidents are likely to occur in the future. See Carburetors, 565 F.2d 754 (engine fires); Pitman Arms, 561 F.2d 923 (loss of control); United States v. Ford Motor Co., 453 F. Supp. 1240 (D.D.C. 1978) (“Wipers”) (loss of visibility); United States v. Ford Motor Co., 421 F. Supp. 1239, 1243–1244 (D.D.C. 1976) (“Seatbacks”) (loss of control). Similarly, where it is alleged that a defect “is systematic and is prevalent in a particular class of [motor vehicles or equipment], . . . this is prima facie an unreasonable risk.” Pitman Arms, 561 F.2d at 929.

III. Guidance and Recommended Best Practices: Safety-Related Defects, Unreasonable Risk, and Emerging Technologies

Consistent with the foregoing background, NHTSA’s enforcement authority concerning safety-related defects in motor vehicles and equipment extends and applies equally to new and emerging automotive technologies. This includes, for example, automation technology and equipment, as well as advanced crash avoidance technologies. Where an autonomous vehicle or other emerging automotive technology causes crashes or injuries, or has a manifested safety-related failure or defect, and a manufacturer fails to act, NHTSA will exercise its enforcement authority to the fullest extent. Similarly, should the Agency determine that an autonomous vehicle or other new automotive technology presents a safety concern, the Agency will evaluate such technology through its investigative authority to determine whether the technology presents an unreasonable risk to safety.

To avoid violating Safety Act requirements and standards, manufacturers of emerging technology and the motor vehicles on which such technology is installed are strongly encouraged to take steps to proactively identify and resolve safety concerns before their products are available for use on public roadways. The Agency recognizes that much emerging automotive technology heavily involves electronic systems (such as hardware, software, sensors, global positioning systems (GPS) and vehicle-to-vehicle (V2V) safety communications systems). The Agency acknowledges that the increased use of electronic systems in motor vehicles and equipment may raise new and different safety concerns. However, the complexities of these systems do not diminish manufacturers’ duties under the Safety Act—both motor vehicle manufacturers and equipment manufacturers remain responsible for ensuring that their vehicles or equipment are free of safety-related defects or noncompliances, and do not otherwise pose an unreasonable risk to safety. Manufacturers are also reminded that they remain responsible for promptly reporting to NHTSA any safety-related defects or noncompliances, as well as timely notifying owners and dealers of the same.

In assessing whether a motor vehicle or piece of motor vehicle equipment poses an unreasonable risk to safety, NHTSA considers the likelihood of the occurrence of a harm (i.e., fire, stalling, or malicious cybersecurity attack), the potential frequency of a harm, the severity of a harm, known engineering or root cause, and other relevant factors. Where a threatened harm is substantial, low potential frequency may not carry as much weight in NHTSA’s analysis. Software installed in or on a motor vehicle—which is motor vehicle equipment—presents its own unique safety risks. Because software often interacts with a motor vehicle’s critical safety systems (i.e., systems encompassing critical control functions such as braking, steering, or acceleration) the operation of those systems could be substantially altered by after-market software updates. Additionally, software located outside the motor vehicle (i.e., portable devices with vehicle-related software applications) could be used to affect and control a motor vehicle’s safety systems. If software has manifested a safety-related performance failure, or otherwise presents an unreasonable risk to safety, then the software failure or safety-risk constitutes a defect compelling a recall.

In the case of cybersecurity vulnerabilities, NHTSA will weigh several factors in determining whether a vulnerability poses an unreasonable risk to safety (and thus constitutes a safety-related defect), including: (i) The amount of time elapsed since the vulnerability was discovered (e.g., less than one day, three months, or more than six months); (ii) the level of expertise needed to exploit the vulnerability (e.g., whether a layman can exploit the vulnerability or whether it takes experts to do so); (iii) the accessibility of knowledge of the underlying system (e.g., whether how the system works is public knowledge or whether it is sensitive and restricted); (iv) the necessary window of opportunity to exploit the vulnerability (e.g., an unlimited window or a very narrow window); and, (v) the level of equipment needed to exploit the vulnerability (e.g., standard or highly specialized).

NHTSA uses those factors, and others, to help assess the overall probability of a malicious cybersecurity attack. The probability of an attack includes circumstances in which a vulnerability has been identified, but no actual incidents have been documented or confirmed. Confirmed field incidents may increase the weight NHTSA places on the probability of an attack in its assessment. Even before evidence of an attack, it is foreseeable that hackers will try to exploit cybersecurity vulnerabilities. For instance, if a cybersecurity vulnerability in any of a motor vehicle’s entry points (e.g., Wi-Fi, infotainment systems, the OB–II port) allows remote access to a motor vehicle’s critical safety systems (i.e., systems encompassing critical control functions such as braking, steering, or acceleration), NHTSA may consider such a vulnerability to be a safety-related defect compelling a recall.

Manufacturers should consider adopting a life-cycle approach to safety risks when developing automated vehicles, other innovative automotive technologies, and safety compliance programs and other business practices in connection with such technologies. A life-cycle approach would include “elements of assessment, design, implementation, and operations as well as an effective testing and certification program.” National Highway Traffic Safety Admin., 80 Federal Register 24873 (June 25, 2015), available at https://www.nhtsa.gov/about-nhtsa/reports/applications/2015-062-docket/.
DEPARTMENT OF THE TREASURY
Office of the Comptroller of the Currency


AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, “Securities Exchange Act Disclosure Rules and Securities of Federal Savings Associations.” The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by May 2, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0106, 400 7th Street SW., Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to prainfo@occ.treas.gov.

You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, (TTY), (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:


OMB Control No.: 1557–0106.

Description: This submission covers an existing regulation and involves no change to the regulation or to the information collection requirements.

The Securities and Exchange Commission (SEC) is required by statute to collect, in accordance with its regulations, certain information and documents from any firm that is required to register its stock with the SEC. Federal law requires the OCC to apply similar regulations to any national bank or Federal savings association similarly required to be registered (those with a class of equity securities held by 2,000 or more shareholders).

12 CFR part 11 ensures that a national bank or Federal savings association whose securities are subject to registration provides adequate information about its operations to current and potential shareholders, depositors, and the public. The OCC reviews the information to ensure that it complies with Federal law and makes public all information required to be filed under the rule. Investors,

Issued in Washington, DC, on March 25, 2016 under authority delegated pursuant to 49 CFR 1.95.

Paul A. Hemmersbaugh,
Chief Counsel.


BILLING CODE 4910–59–P
