

**OFFICE PROCEDURES
FOR CONDUCTING
DEFECT INVESTIGATIONS**

June 2010

**Office of Defects Investigation
National Highway Traffic Safety Administration**

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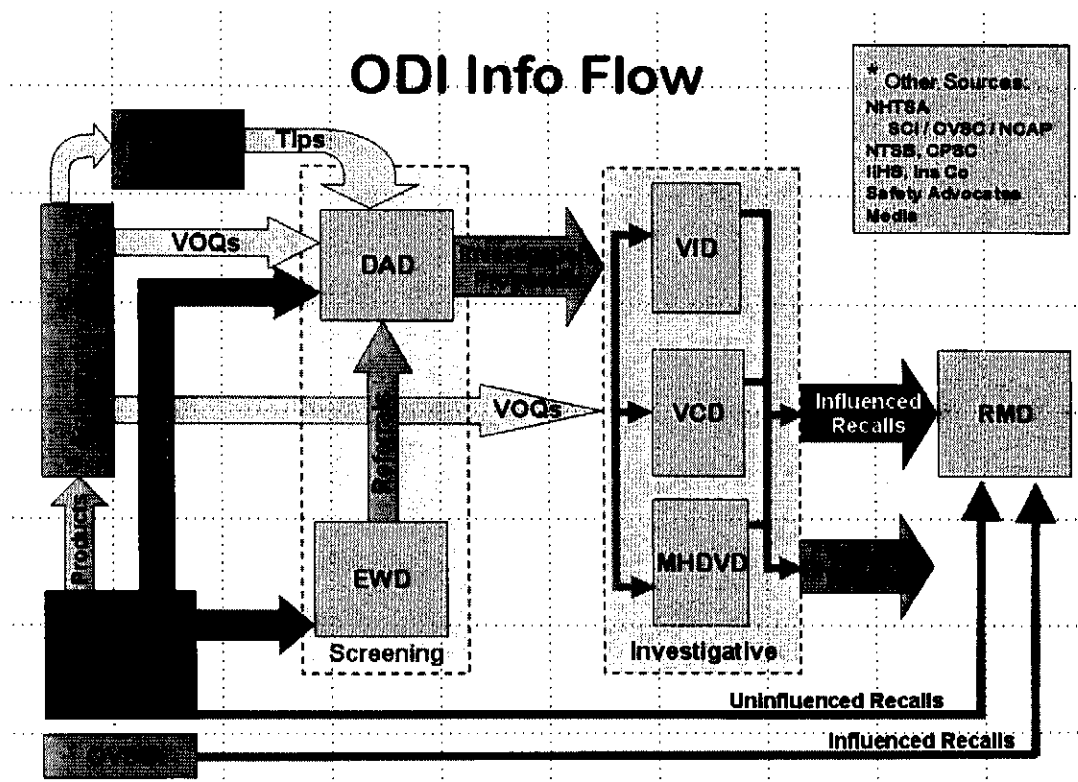
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1.0 INTRODUCTION

The Office of Defects Investigation (ODI) investigative process consists of several elements as follows:

- (1) Early Warning Assessment -- a preliminary review of Early Warning Reporting (EWR) information;
- (2) Defects Assessment -- a review of consumer complaints, external manufacturer communications, and other information related to alleged safety defects so that ODI can decide whether to open an investigation, grant a petition for a defect investigation, determine the adequacy of safety recalls, and grant a petition for a public hearing on the adequacy of a safety recall;
- (3) Investigation -- the formal investigation of alleged safety defects and/or recall adequacy;
- (4) Recall Management -- the monitoring of safety defect and non-compliance recalls for compliance with statutory and regulatory requirements, and
- (5) Correspondence Research Division (CRD) which responds to, captures and stores (for future access) complaints about potential safety defects.

This document describes the Investigation element in detail and gives a brief description of the others.



ODI's objective is to assure that vehicles and equipment with safety-related defects are recalled in accordance with Chapter 301 of Title 49 of the United States Code. Under that law, NHTSA may require a manufacturer to conduct a recall only if the agency can establish that a defect exists and it is "related to motor vehicle safety." A defect is a problem in the performance, construction, a component, or material of a motor vehicle or motor vehicle equipment. To demonstrate that a problem is a defect NHTSA must be able to show that there is the potential for a significant number of failures. To establish that the defect is related to "motor vehicle safety," NHTSA must be able to show that the defect presents an "unreasonable risk" of an accident, injury, or death. Motor vehicle safety includes nonoperational safety of a motor vehicle.

Risk Analysis in the Defect Investigation Process

Because "unreasonable risk" is the basic legal standard ODI has to apply in its investigative work, determining the level of risk posed by a particular defect is essential to deciding whether a defect warrants a recall. As used here, ODI generally uses the term "risk" to mean the total exposure to unsafe consequences that may be assumed to exist when both the likelihood and severity of a defect are considered. The concept is often represented by the simple equation "risk = [likelihood of occurrence] x [severity of consequences]." The central idea is that risk in any setting is a product of both the likelihood of the hazard and its potential severity.

Accordingly, as part of its methodology, ODI routinely uses risk analysis principles to:

1. identify potential defect issues as deserving of investigation;
2. estimate the likelihood and severity of the defect to help determine whether it involves unreasonable risk and distinguish which investigations need priority treatment;
3. propose an action based on the information obtained during the investigation;
4. decide what action to take: close, upgrade or recall. The investigative risk analysis processes are shown in Figure 1 (Page 10).

Risk analysis principles are commonly used in the federal government as a tool for analyzing health and safety risks, particularly in the rulemaking context.¹ Some DOT agencies make extensive use of these principles in their safety programs.²

Several factors make ODI's use of risk analysis principles somewhat unique. Unlike an agency that is trying to determine how to proceed on a rulemaking intended to set broadly applicable standards on a particular subject, ODI is constantly analyzing risk in dozens of different contexts

1 For example, see the Office of Management and Budget's *Principles for Risk Analysis*, http://www.whitehouse.gov/omb/inforeg/regpol/jan1995_risk_analysis_principles.pdf, and *Updated Principles for Risk Analysis*. http://www.whitehouse.gov/omb/pubpress_2007_091907_risk_analysis/

2 FAA's system safety handbook is an example. See http://www.faa.gov/library/manuals/aviation/risk_management/ss_handbook/

related to particular vehicles, items of equipment, and components. Because ODI's goal is to identify and address these discrete risks as quickly as possible, there is no opportunity to conduct the type of lengthy, complex, peer-reviewed risk analyses that may be appropriate in other contexts. Moreover, particularly at the screening stage, choices have to be made without the luxury of complete data development. Even during an investigation, data may be quite limited, and the picture they present may change greatly over the course of an investigation. Therefore, while all available data are analyzed, ODI does not attempt to quantify risk on a standardized scale. Instead, its risk analyses entail a great degree of expert judgment based on ODI's experience with similar matters. Rather than quantify risk, ODI's analyses are intended to yield a general characterization of the level of risk posed by a given defect to enable ODI to allocate its resources appropriately and know which defects are likely to satisfy the qualitative statutory standard of "unreasonable" risk.

In every investigation, ODI looks at a range of factors to determine the defect's likelihood of occurrence, including:

- Complaint rates (both VOQs submitted to NHTSA and company data)
- Warranty rates
- Field report data
- Property damage data

In looking at the severity of a defect, analysis is complicated because the defect's occurrence does not always have a safety consequence that has been realized (e.g., a wheel may crack without causing a loss of control), and the defect may have a range of consequences of varying severity (e.g., temporary loss of power, stalling, or loss of control). In many possible safety defect situations, crashes or injuries are very few in number or have not yet occurred at all, so estimating risk based merely on crash data would be misleading and likely to delay effective action that may avoid crashes, injuries, and other bad consequences. Therefore, the ODI investigator needs to look at both actual consequences (deaths, injuries, crashes, fires, etc.) and the range of potential consequences.

In weighing a defect's potential consequences, interviews with complainants are a good source, because they may reveal occurrences where unsafe consequences were narrowly avoided (referred to as near misses or "white knuckle" experiences). Such instances can be very helpful in demonstrating the level of risk that exists even in the absence of substantial crash or injury data. In addition to the risk posed by the defect in its present context of a particular vehicle, it is also useful to know whether the same or similar defects have resulted in unsafe consequences in other vehicles or similar contexts. For example, NHTSA's extensive accident data bases may contain useful information on the "generic risk" posed by a certain type of defect or particular type of consequence. FARS and NASS-CDS are excellent sources of such data concerning highway crashes concerning circumstances similar to those under investigation. For example, the number of deaths and serious injuries resulting from disabled vehicles being struck in or near the roadway may help demonstrate that a defect that results in a vehicle's disablement while being

driven at highway speeds could result in very serious consequences. Similarly, the NITS data base, which contains data on incidents occurring off the highway (such as entrapment of children in a vehicle) or non-crash incidents (such as fires) on the highway, may be very helpful in some investigations.

The ODI investigator needs to be able to pull together the available data into a coherent analysis and apply professional judgment in supporting his or her preliminary conclusion as to how to characterize the risk in a particular situation. The history of similar investigations is informative as to where the agency has and has not determined unreasonable risk to exist. However, those previous investigations are not binding precedent, and the investigator needs to be able to articulate, by blending the available information on likelihood and severity, whether and how the defect being investigated poses such a risk. To provide a standardized format for summarizing the status of an investigation, investigators should use the Investigation Overview (attached) when presenting the status of an investigation along with any additional materials they find helpful.

By using the investigative process described in this document, defects that are related to motor vehicle safety can be identified. The process encompasses all aspects of investigating, analyzing and evaluating defects necessary to determine whether a safety-related defect exists in motor vehicles or items of motor vehicle equipment.

A brief description of the above-mentioned investigative process elements is given below:

1.1 Early Warning Reporting Assessment

Early Warning Reporting (EWR) information, including aggregate data, death and injury data, foreign campaigns, and field reports, is reviewed by the Early Warning Division (EWD). If EWD discovers a statistical anomaly in the aggregate data, an issue in a foreign campaign that might be applicable to substantially similar vehicles or equipment sold in the United States, or an issue in one or more field reports or notices of a death that could potentially indicate a safety-related problem, EWD sends an information request letter to the manufacturer requesting clarification of the information. If that clarification supports the premise that a safety-related defect could exist in a motor vehicle or motor vehicle equipment, that information is provided to the Defects Assessment Division.

EWD also administers the EWR program by performing outreach to ensure that all manufacturers are aware of their reporting responsibilities. EWD also ensures that manufacturers required to submit EWR data follow the appropriate procedures and data submitted is complete.

1.2 Defects Assessment:

Under the Defects Assessment process, available information -- including but not limited to EWR data, manufacturer service bulletins, Electronic Vehicle Owner's Questionnaires (EVOQs), Vehicle Owner's Questionnaires (VOQs), E-mail, verbal consumer complaints, letters, and anonymous reports -- is reviewed by the Defects Assessment Division (DAD). If DAD believes that the available information indicates that a safety-related trend may be developing, a staff

analyst prepares an Initial Evaluation (IE) Resume and a memo report that summarizes the available information. The appropriate investigative Division (Vehicle Control Division (VCD), the Vehicle Integrity Division (VID) or the Medium & Heavy Duty Vehicles Division (MHDVD) is notified and the Defects Assessment Review Panel is convened to review the IE and to decide whether to open an investigation.

Pursuant to 49 U.S.C. § 30162 and 49 CFR Part 552, any person may submit a petition requesting NHTSA to commence an investigation into an alleged safety defect. After conducting a technical analysis of such a petition, ODI informs the petitioner whether it has been granted or denied. If the petition is granted, an investigation is opened and is conducted by the appropriate Investigative Division. If the petition is denied, the reasons for the denial are published in the *Federal Register*. Additionally, pursuant to 49 U.S.C. § 30118 (e) and § 30120 (e) (49 CFR Part 557), a person may submit a petition requesting NHTSA to hold a hearing regarding the adequacy of a recall notification or remedy.

(See Defects Assessment Control Plan for additional detail.)

1.3 Investigations:

Investigations are generally conducted in two phases: the Preliminary Evaluation (PE) and the Engineering Analysis (EA). Most PEs are opened following a review of a concern by DAD, but some are opened on the basis of other information. During the PE phase (see section 2.1), ODI sends an information request letter (IR letter) to the manufacturer and obtains information that includes, but is not limited to, data on complaints, crashes, injuries, warranty claims, modifications, and part sales. In the response to ODI's IR letter, the manufacturer has an opportunity to present its views regarding the alleged defect. PE's are generally resolved within four months from the date they are opened. They may be closed on the basis that further investigation is not warranted, or because the manufacturer has decided to conduct a recall. In the event that ODI believes further analysis is warranted, the PE is upgraded to an EA.

ODI also opens new investigations based on complaint reports or other information received concerning a recall action. Reports or other information provided to the agency may indicate that the recall remedy could be inadequate or that the scope of the recall may be insufficient to address the problem. An investigation opened based on a recall is called a Recall Query (see section 2.2). The Recall Query (RQ) is conducted in a manner very similar to the PE investigation. An RQ investigation may be upgraded to an EA if ODI believes that the issue warrants further study.

During an EA (see section 2.3), ODI conducts a more detailed and complete analysis of the character and scope of the alleged defect. The EA builds on information collected during the PE and supplements it with appropriate inspections, tests, surveys, and additional information obtained from the manufacturer, manufacturers of peer vehicles or equipment and suppliers. ODI attempts to resolve all EAs within one year from the date they are opened, but some complex investigations require more time. At the conclusion of the EA, the investigation may be closed without further action. However, if ODI believes that the data developed indicate that a

safety-related defect exists, the Senior Associate Administrator (SAA) for Vehicle Safety and the Associate Administrator (AA) for Enforcement are briefed. With their concurrence, the ODI investigator prepares a briefing to be presented to the Multi-Disciplinary Review Panel (a panel of experts from throughout the agency) for peer review (see section 2.5).

The manufacturer is notified (verbally) that a panel will be convened and the date when the panel will be held. Prior to the panel, if the manufacturer desires to present new analysis or data to the agency, the ODI staff will evaluate that information and include it in the panel discussion. After the panel is held, ODI informs the manufacturer of the outcome.

ODI evaluates the recommendation or concerns raised by the panel and decides whether to send a Recall Request Letter (see section 3.0). ODI will verbally inform the manufacturer of its intention to send the Recall Request Letter (RRL), usually within 10 days. If the manufacturer declines to conduct a recall in response to the RRL, the Associate Administrator for Enforcement or his delegate may issue an Initial Decision (see section 4.0) that a safety-related defect exists. An Initial Decision will be followed by a Public Meeting, during which the manufacturer and interested members of the public can present information and arguments on the issue. Written materials may also be submitted. The entire investigative record is then presented to the NHTSA Administrator, who may issue a Final Decision (see section 5.0) that a safety defect exists and order the manufacturer to conduct a recall.

Figures 2, 3 and 4 provide a graphic overview of the investigative process and illustrate the major documents produced during investigations. A recall can occur at any point during this process.

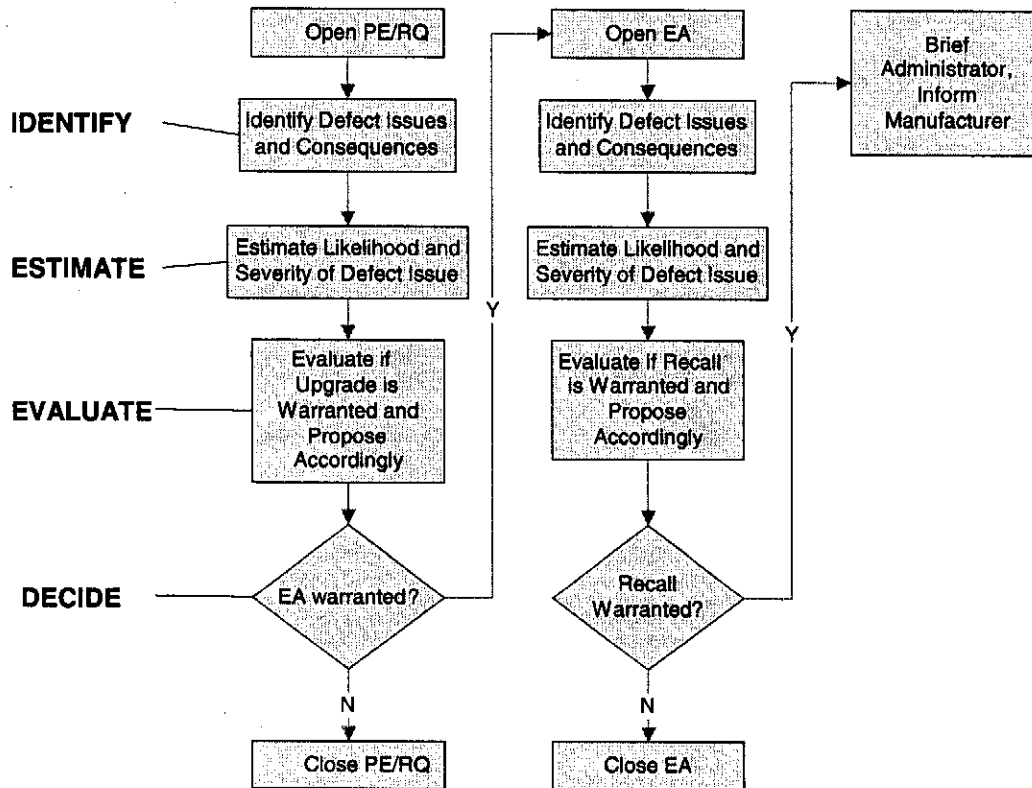
1.4 Recall Analysis:

The Recall Management Division (RMD) maintains the administrative file for all safety recalls, and monitors these recalls ensuring that manufacturers conform to statutory and regulatory requirements and that the recall completion rate is adequate. (See Recall Management Control Plan for additional detail.)

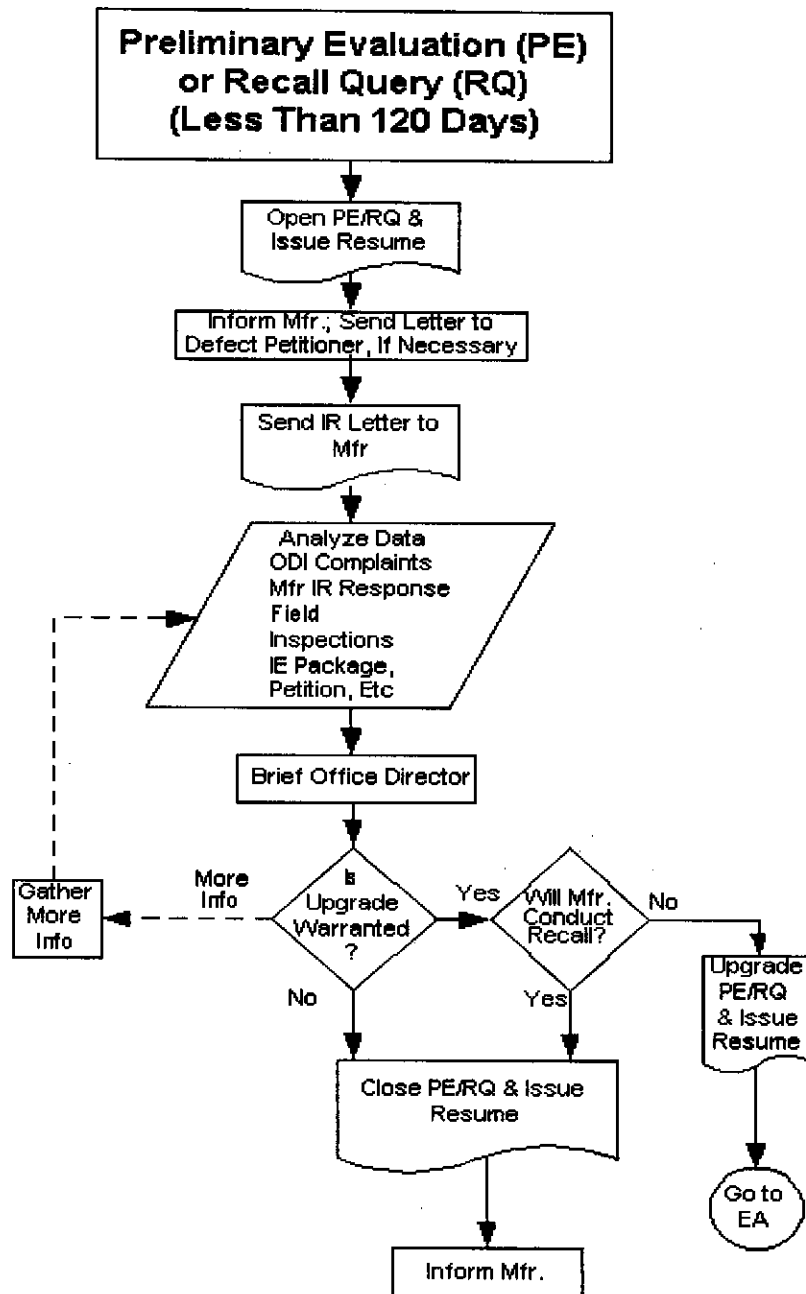
1.5 Correspondence Research Division

The Correspondence Research Division (CRD) reviews all incoming correspondence and prepares replies where appropriate. VIP correspondence is researched in detail and all such correspondence receives an appropriate reply. All correspondence is entered into the ODI complaint database system as appropriate and complaints are examined for potential defects. Issues identified as an immediate concern are brought to the attention of the Defects Assessment Division or Recall Management Division. CRD also prepares public copies of investigation case files ensuring that all personal identifiers and business confidential information are permanently redacted before public dissemination.

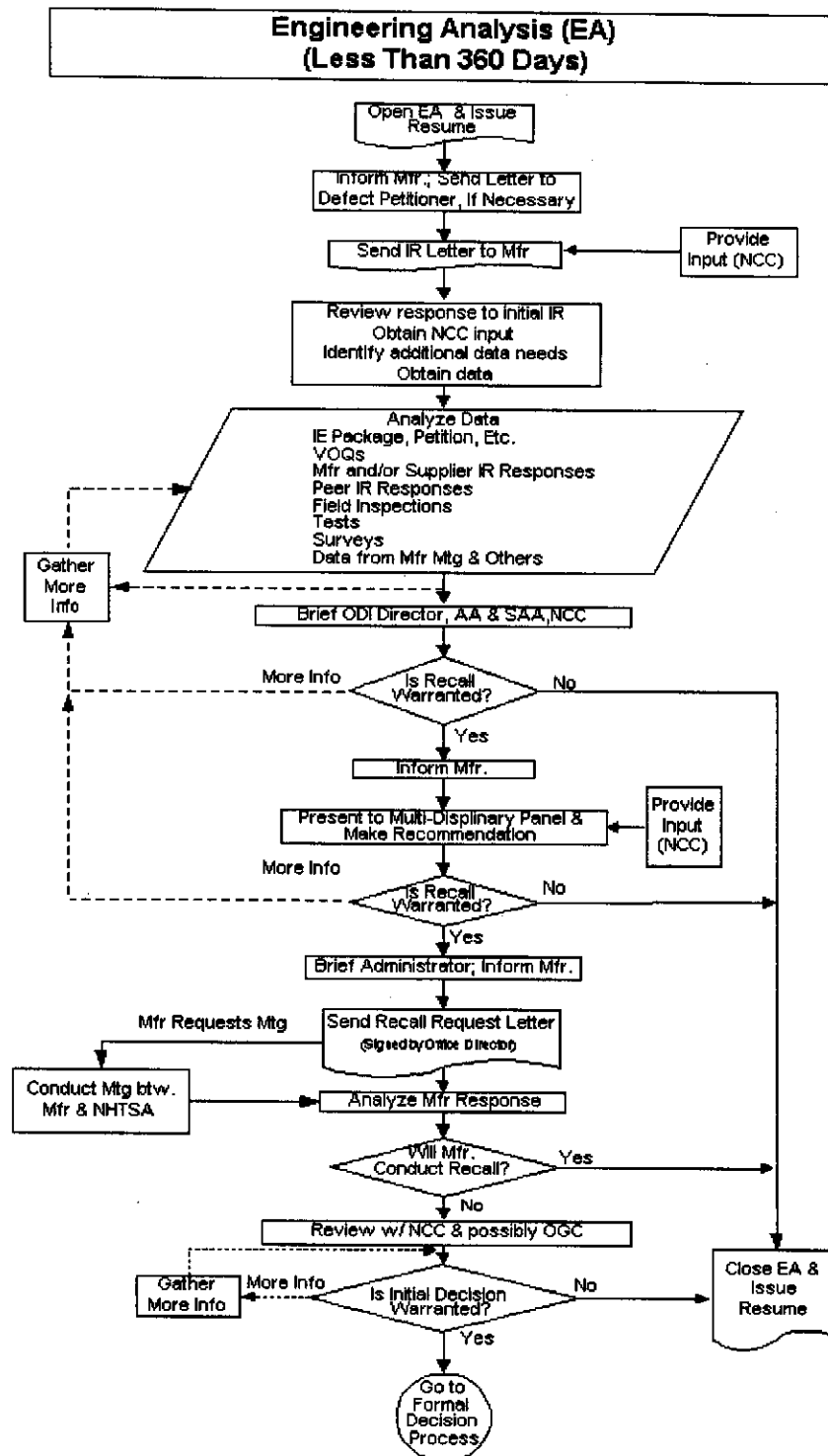
Risk Analysis



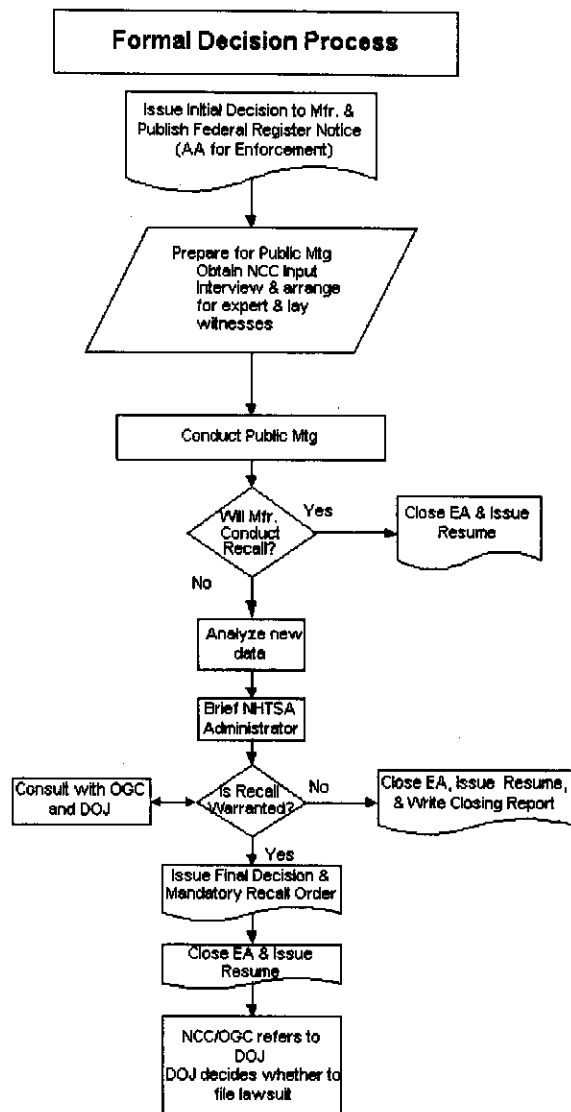
Investigative Risk Analysis Process
Figure 1



Preliminary Evaluation/Recall Query Process
Figure 2



Engineering Analysis (EA) Process
Figure 3



Formal Decision Process
Figure 4

2.0 INVESTIGATIVE PROCEDURES

This section provides a detailed description of the procedures used in conducting each phase of the investigative process.

These procedures provide a set of "standard office practices" which are generally followed by ODI investigators. They are meant to guide internal ODI activities, and deviations from these procedures cannot be used by manufacturers or other interested persons to challenge ODI or NHTSA decisions. Modifications may be made under appropriate circumstances, provided that they are consistent with the authorizing statute and with agency regulations and orders. Investigators are encouraged to be innovative in their approach to investigations by omitting procedures that are not applicable or are unlikely to yield useful information, and by adding elements that are likely to aid in the resolution of the investigation. Even investigations on similar subjects are slightly different at the micro-level and they all require slightly different approaches as dictated by the facts. Generally, the appropriate Division Chief must approve such modifications. Investigators are expected to use initiative in fulfilling their responsibilities in completing investigations in a timely manner.

Note: In the rare situation where the safety risk appears to be extremely high based on analysis of a defect's likelihood and severity, the Division Chief should consult the Office Director and Associate Administrator for Enforcement. Together, with advice from the Office of Chief Counsel, they will find ways to expedite resolution of the matter to ensure that the risk is addressed as soon as possible. In such a case, ODI will inform the manufacturer that it intends to move through the investigation in an expedited manner.

During each investigation, the investigator shall develop an informal analysis of the risk presented by the alleged defect. The analysis should include characterization of the frequency and severity of the alleged defect. The frequency assessment should provide the reviewer with actual or estimated failure rates at various service intervals of interest for the subject vehicles and any subpopulations of interest, as well as data from peer vehicles and from prior investigations for comparison. In addition to failure rate analyses, the frequency assessment should also include an assessment of the failure trend (i.e., increasing, decreasing or constant as a function of time in service or mileage). The severity assessment should provide the reviewer with an analysis of the harm that has resulted from the failures that have already occurred and the potential for harm to occur with continued failures if the condition is not remedied. The harm should be measured not simply by the number of crashes, fires and injuries (which in many cases may not yet have occurred), but also by their severity, or potential severity.

Frequency analyses should be performed using the full scope of complaint, field report, warranty and other field data (e.g., crash data), as appropriate, that are associated with the alleged defect in the subject vehicle population and, if warranted, various subpopulations (e.g., by region, production range, production plant, vehicle attribute or design level). The investigator should consider comparing the data with peer data or data from prior related investigations. In some

investigations it may be useful to conduct surveys of randomly selected subject vehicle owners as another means of assessing frequency, particularly if the alleged defect tends to occur after the warranty period expires or is an issue not generally covered by warranty repair.

Severity assessments should begin with a basic statement of the potential safety risk(s) created by the alleged defect, based on complaint allegations and/or engineering judgment. Severity analyses should be performed using the following methods, as appropriate: (1) analysis of all actual crashes, fires, (or other field experiences) injuries and deaths that may be related to the alleged defect; (2) a random survey of drivers, or other individuals, who experienced the alleged defect to assess the proportion of failures that created potentially harmful circumstances to the subject vehicle occupants or to other motorists or pedestrians; (3) an analysis of generic crash, fire, or other field data to estimate the annual crash, fire, injury and death experience in similar events; (4) an analysis of prior related investigations and recalls; (5) testing; or (6) other methods appropriate to specific defect issues.

Note: Certain kinds of defects will be of such great actual or potential severity that little is needed in terms of frequency data to support a determination of unreasonable risk. A fundamental principle of risk analysis is to think of the overall risk as the product of the defect's frequency times its severity. That is, if severity is extremely high the overall risk will be high even if the number of occurrences is small. For example, a demonstrated defect that clearly results in total loss of control of the vehicle or a vehicle fire would likely warrant a recall even if it had happened infrequently. While the investigator needs to make every effort to determine frequency in such situations, the emphasis should be on the inevitable severity of the situation when the defect does occur. Such very high severity matters should be candidates for expedited treatment, as discussed above.

2.1 Preliminary Evaluation (PE)

The PE is usually the first phase of an investigation by ODI concerning an alleged defect. A PE may be opened when the possibility exists that vehicles or items of equipment contain a defect in performance, design, construction, or material that is related to motor vehicle safety. Most PEs are opened following a review of available information by DAD. Others may be opened on the basis of (1) a recommendation from a member of one of the Investigative Divisions, or (2) a grant of a petition to investigate an alleged safety defect or the adequacy of a safety recall. The ODI Office Director must approve the opening of a PE.

When a PE is opened, a PE Opening Resume is prepared by the assigned investigator. The Resume describes the alleged defect and summarizes the relevant information known to ODI at the time. The PE Opening Resume must be reviewed and signed by the appropriate investigator, Investigative Division Chief and the Office Director. PEs are assigned investigative numbers after they are approved by the Office Director. ODI attempts to notify the manufacturer by phone or email that a PE has been opened and that an Information Request (IR) is being prepared. A copy of the Resume is faxed to the manufacturer.

Soon after opening a PE, the IR is prepared and sent to the manufacturer. The IR letter requests information and documents concerning, ordinarily at a minimum, vehicle population, complaints, crashes, fires, injuries, fatalities, and lawsuits known to the manufacturer that are relevant to the alleged defect, as well as any analyses by the manufacturer of the alleged defect. ODI writes many of its IR questions from a template so as to facilitate the prompt issuance of the IR, and to reduce the need for interpretation by the manufacturer and the likelihood of misunderstanding the request. Also, the investigator should not include in the PEIR letter, questions that are likely to be irrelevant to the fundamental issue of whether the investigation should be closed or upgraded to an EA. At the same time, there will be situations where it is appropriate to include additional questions in the IR letter in order to get at the heart of a particular matter. Such questions may concern Technical Service Bulletins, warranty data, design changes, and other relevant information. If there are any issues about how best to draft IR questions, the investigator should consult the Division Chief and NCC. Copies of relevant consumer complaints that have been received by ODI are sent to the manufacturer for its review along with the PE Information Request (PEIR), with personal identifiers deleted or released in accordance with Privacy Act guidance for the Office of Defects Investigation.

ODI opens a public file for the PE and places a copy of the resume, IR letter and consumer complaints with personal identifiers redacted into the file. ODI staff maintains the public file. The file is available for viewing on the ODI web site and at NHTSA's Technical Information Services (TIS) viewing room. In addition to the Resume, written communications between ODI and the manufacturer during the course of the investigation and other appropriate documents, are placed in the Public File, except for confidential documents.

If clarification or additional work is needed to conclude the PE, the investigator and Division Chief will develop a plan to obtain the necessary information, and the Office Director will be apprised. On some occasions, a follow-up IR may be sent. If the investigator and/or the Division Chief believe the decision on whether to upgrade or close is complex or raises important policy issues, a technical briefing for the Office Director and/or the Associate Administrator may take place.

Based on the analysis of the manufacturer's response, and other available information, the PE may be: (1) closed on the basis that further investigation is not warranted, (2) closed because the manufacturer has decided to conduct a recall, or (3) upgraded to an EA because additional and more detailed analysis is necessary. Under either of the first two scenarios, the investigator prepares a Closing Resume, which identifies and describes the basis for closing the investigation.

If the investigation is to be upgraded to an EA, the investigator prepares a PE Closing Resume and an EA Opening resume, which document the reasons for upgrading the PE to an EA. The investigator, the Division Chief, and the Office Director must sign Opening and Closing Resumes. ODI administrative staff faxes or emails a copy of Opening and Closing Resumes to the manufacturer. All resumes are placed in the Public File. The action is effective on the date the Office Director signs the Resume.

2.2 Recall Query (RQ)

The Defect Assessment Division also reviews complaints that are reported to the Agency regarding problems encountered by vehicle owners with a motor vehicle or item of motor vehicle equipment that has been recalled. An investigation opened in response to recall-related complaints is a Recall Query. The Office conducts an RQ investigation in a manner very similar to the PE investigation. The RQ investigation includes informal risk analysis, similar to that discussed in Section 2.0. The investigator prepares an RQ Opening Resume that is reviewed and signed by the investigator, the Division Chief and the Office Director. Next, the investigator prepares an IR that includes questions similar to the PE IR letter but usually contains more specific technical questions based on the defect and remedy of the recall. The letter may also contain questions concerning the scope of the recall. The RQ may be closed or upgraded to an Engineering Analysis (EA) based on the review of the manufacturer's response and all other information. The investigator prepares a Closing and an Opening Resume, as appropriate.

2.3 Engineering Analysis (EA)

As noted above, most EAs are opened following the completion of a PE or RQ. The EA ordinarily will have the same or a similar alleged defect as its preceding PE or RQ investigation. Other EAs are opened on the basis of a grant of a petition for a defect investigation (DP) or grant of a recall petition (RP). In rare circumstances, an EA may be opened without a prior PE or other preliminary investigation. EAs are assigned investigative numbers after they are approved by the Office Director.

When an EA is opened, an EA Opening Resume is prepared by the investigator. The Opening Resume is reviewed and approved by the appropriate Division Chief and the Office Director. ODI notifies the manufacturer by phone or email that the investigation has been upgraded to the EA level and that an additional information request may be forthcoming. A copy of the Resume is faxed to the manufacturer, and a new, separate Public File is opened.

At the outset of the EA, ODI informs NCC of the new open EA investigation. NCC assigns an attorney to work with the ODI investigator on the investigation. The NCC attorney will provide legal input during the investigation, particularly for the EA IR letter, or any survey and testing deemed necessary. Likewise, NCC will participate in review of the data and facts gathered during the investigation.

Some or all of the following actions may be taken during the EA, depending upon the particular circumstances:

- In virtually all cases, an EA Information Request (EAIR), with copies of additional consumer complaints, is sent to the manufacturer. This request may ask for clarification of previous responses; updated information regarding sales figures, consumer complaints, field reports and lawsuits; warranty experience; material changes; component

modification history; manufacturer's test results; and other detailed, technical questions pertaining to the alleged problem and its causes. If it has not previously been provided, the manufacturer's assessment of the problem is requested at this time. Later in the investigation, one or more follow up IR letters may be issued to the manufacturer, to obtain additional information or updated information or both.

- The ODI databases are checked for (1) additional consumer complaints, (2) manufacturer service bulletins, (3) previous ODI investigations into problems that may be similar to the alleged defect, (4) updated EWR information and (5) pertinent recalls (both for the subject vehicle manufacturer and peer vehicle manufacturers).
- Consumers who have reported the problem to ODI may be contacted in order for ODI to better understand the matter under study. At times, interviews are conducted at the beginning of the investigation to gain a general understanding. If necessary, a second and more structured round of interviews is conducted later in the investigation. Contractors, staff from NHTSA's Vehicle Research and Test Center (VRTC) in East Liberty, Ohio, ODI staff or NCC staff may conduct these interviews or special surveys involving the subject vehicles, as appropriate.
- Crash data (from, e.g., the Fatal Analysis Reporting System (FARS), National Automotive Sampling System (NASS), and State files) may be obtained from NHTSA's National Center for Statistics and Analysis (NCSA), and relevant literature may be obtained from TIS.
- Test programs may be conducted for a variety of purposes. These purposes include, but are not limited to, identification of the specific failure mode, determining the scope of the alleged defect, comparison with peer vehicles/components, simulation of the failure to determine potential safety consequences, etc. Such testing is normally performed at VRTC, but outside contractors may be used where circumstances warrant.
- If the alleged problem involves a specific component or assembly, IRs may be sent to the supplier(s) of the component(s). Similarly, IRs may be sent to other vehicle manufacturers who use the allegedly defective component(s) in their products.
- IRs may be sent to manufacturers of similar ("peer") vehicles to ascertain rates of problems in peer vehicles for comparison with the vehicles covered by the investigation, or for other reasons. "Peer IRs" should not suggest that the agency believes there are problems with the peer manufacturer's products.
- ODI will make an assessment of the manufacturer's position regarding the alleged defect.

The information gathered through these techniques is analyzed to determine the likelihood and severity of the alleged defect and its safety relatedness. The investigator may consider some or all of the following factors:

- Failure history and projections, based on warranty claims, time-to-failure, mileage at failure, parts sales, and vehicle population.
- Circumstances in which the defect manifests itself.
- Nature and severity of the problem.

- Possible causes of the failure and failure modes; e.g., are there broken parts?; are there quality control issues?; does the alleged defect appear to be related to a design feature? (NHTSA is not required to prove the root cause, but sometimes it is helpful to identify it).
- The implications of differences in vehicle components (e.g., failures concentrated in vehicles with particular engines, transmissions, or other features) or in manufacturing history (e.g., manufacturing date).
- Possible contributing and causal factors, such as environmental conditions (including road surface treatment (e.g., salt) and temperature).
- Engineering issues, such as the relationship between design, material, or manufacturing changes and the failure history and modifications.
- Issues related to the regional incidence of problems and a potential regional recall.
- Safety-related implications, including an informal analysis of safety risk based on discussion of frequency and severity of unsafe consequences that have already occurred ("realized" risk) and additional unsafe consequences that are likely to occur (potential risk).
- Comparison with "peer groups." How do the subject vehicles compare to contemporary "peer" vehicles and/or components, to vehicles/components covered by previous ODI investigations, and for vehicles that were recalled previously to correct apparently similar problems?

ODI's goal is to complete EAs within 12 months of opening. However, that is dependent on many factors, such as scope of the investigation, number of complaints, technical complexity, responsiveness of the manufacturer, etc.

If the results of the investigation indicate that it should be closed with no further action, an EA Closing Report and a Closing Resume are prepared by the investigator, reviewed by NCC and approved by the Division Chief and the Office Director. The Report should include a discussion as to the problem experience of the vehicle/equipment at issue, and describe the work performed during the EA. Where appropriate, if there is a defect the Report should also include a discussion of the risk to motor vehicle safety created by the alleged defect. The Report and the Resume become public documents; they ordinarily should contain no judgments, opinions, or recommendations other than those necessary to provide a rationale for the decision to close. The action is effective on the date that the Office Director signs the Closing Resume.

If, during the investigation, a manufacturer initiates a recall that is sufficient to resolve the issues under investigation, the EA may be closed with a Closing Resume that discusses the important facts concerning the recall. Under that circumstance, an EA Closing Report is not required.

If the results of the EA lead ODI to believe that there is a safety-related defect and the manufacturer has not conducted a recall, a Multi-Disciplinary Review Panel (Panel), consisting of NHTSA staff who are familiar and others that aren't familiar with the issues raised by the investigation, will be convened to consider what further action would be appropriate. In preparation for the panel, ODI will prepare a full analysis of the facts and issues developed

during the investigation and review this material with an attorney from the Litigation Division of the Office of Chief Counsel. ODI then briefs the AA for Enforcement and the SAA for Vehicle Safety. After conferring with NCC and briefing the AA and SAA, ODI will convene a panel.

2.4 Information Request Response Times

Generally, domestic manufacturers are allowed six (6) weeks and foreign manufacturers seven (7) weeks to respond to a PEIR. Because EAIRs generally include more questions than PEIRs and those questions are usually of greater complexity, domestic manufacturers are usually given seven (7) weeks, and foreign manufacturers eight (8) weeks, to respond. The response time will generally be shorter for follow-up IRs, since they normally seek a limited amount of information.

The IR should state that if the manufacturer finds that it cannot provide all the requested information within the allotted time, it may request an extension from the appropriate Division Chief. The Division Chief should grant extensions when appropriate. However, in order to conclude these investigations as quickly as possible, extensions should be granted on a case-by-case, as-needed basis. In cases where a manufacturer cannot complete its response by the original due date, the manufacturer should be advised to provide the portion of the response that is complete on the scheduled due date. The IR should include standard language reminding the manufacturer that, by statute, the failure to provide timely, complete, and accurate responses can result in the imposition of civil penalties. If questions arise about the proper interpretation of an IR, the investigator should work with NCC to ensure a complete understanding of what the manufacturer is expected to provide.

If several IRs are sent to the same manufacturer simultaneously and/or a particularly complex request is sent, additional time may be granted for the manufacturer's initial response at the discretion of the Office Director. In addition, extra time normally will be added to all response times to accommodate a manufacturer's shutdown periods.

2.5 Multi-Disciplinary Review Panel

The Panel is generally composed of representatives from the Office of the Administrator (NOA), Chief Counsel (NCC), and several technical offices, such as Vehicle Safety Compliance (NVS-220), Rulemaking (NVS-100), Planning Evaluation and Budget (NPO-300), Vehicle Safety Research (NVS-300), and Traffic Injury Control (NTI-010). The particular individuals are chosen based on their qualifications to conduct a technical review of the issues raised during the investigation. A representative from the Office of Communications and Consumer Information (NPO-500) normally attends as well, for informational purposes only.

Prior to the Panel meeting, the manufacturer is verbally advised of the upcoming meeting. Also, prior to the meeting, appropriate materials are provided to each of the Panel members. The ODI staff investigator conducts the briefing for the Panel, which must include a clear presentation of relevant facts. This will normally include:

- A description of the subject vehicles, including make, model, model year, population, etc.
- A detailed description of the problem, including a description of the alleged defect, its likely symptoms and safety related consequences.
- A comprehensive description of the component involved, including its function, where it is located, and its relationship to the alleged defect.
- A presentation of actual components (where feasible), or sketches, photographs, or models, to illustrate the alleged defect.
- An analysis of the reported failures, by date of incident and by source (ODI, manufacturer, consumer groups, etc.) and the anticipated future failure trend.
- Identification of any known design or manufacturing changes, including a description of the likely effect of the changes on the failure rate and (if available) on performance.
- Service Bulletins and other manufacturer/dealer communications.
- Results of telephone and other surveys conducted during the investigation.
- Results of tests conducted during the investigation.
- Where relevant and available, "peer group" analyses comparing failure or complaint rates of the subject vehicles with other appropriate vehicle groups, based on make, model, model year, and other considerations.
- Identification of prior investigations of similar alleged defects and their outcome, and previous pertinent safety recall campaigns by this manufacturer and others.
- A discussion of the risk to motor vehicle safety associated with the alleged defect, including a characterization of both the frequency and severity of the defect.
- A discussion of the manufacturer's position regarding the alleged defect, including, where applicable, its analysis of the risk to motor vehicle safety.

At the end of the presentation by the investigator, the Panel discusses the issues and can ask ODI for further information/explanation. If the Panel concludes that more information or further analysis is required, the investigation is resumed to address those unresolved issues.

If the Panel believes that a safety recall appears to be warranted, the ODI staff will brief the NHTSA Administrator (or his or her delegate). The ODI Director advises the manufacturer by telephone of the panel result and that a Recall Request Letter (RRL) will be sent, usually within 10 days. However, if the manufacturer requests a meeting for further technical discussions or to discuss a possible recall, ODI may defer the issuance of the RRL.

3.0 RECALL REQUEST LETTER

If the manufacturer declines to determine that a defect exists after being advised that the Panel believes that a safety recall is warranted, the Director of ODI will send a recall request letter.

The RRL is short and concise. It states the basis for ODI's belief that the product contains a safety-related defect and requests that the manufacturer undertake a recall of certain specified

vehicles or equipment items. The letter explicitly states that it should not be construed as an agency "decision" that a defect exists pursuant to 49 U.S.C. § 30118. The RRL is to be signed by the Office Director, with concurrence by the SAA for Vehicle Safety, the AA for Enforcement and the Office of Chief Counsel.

The letter gives the manufacturer 10 working days to indicate whether it will take the requested action. It also directs the manufacturer to explain in detail the basis for any refusal to take the requested action.

4.0 INITIAL DECISION

If the manufacturer rejects ODI's recall request, and it is still ODI's opinion (after reviewing the manufacturer's reasons for refusing to make a defect determination) that a safety defect exists, the ODI investigator prepares an Engineering Action Report with the assistance of the staff attorney assigned to the investigation. The EA report documents the facts and technical analysis of the alleged defect. It provides an overview of the manufacturer's analysis and states the recommendations of ODI. Based on these known facts, the Associate Administrator for Enforcement must decide whether to issue an "Initial Decision" that a safety-related defect exists. Senior agency management must be briefed before such a decision is issued.

The following procedure is used when, after a thorough review of the entire investigative file, the AA for Enforcement makes an Initial Decision, pursuant to 49 U.S.C. §30118(a) and 49 CFR 554.10, that the vehicles or equipment items in question contain a safety-related defect:

1. The investigator ensures that the index of the items in the investigative file is complete. NCC then determines (consistent with the Freedom of Information Act (FOIA), 18 U.S.C. § 1905, and applicable evidentiary privileges) which items should be placed in the "public file" that is to be provided to the manufacturer and made available to the public. The public file must include "the information on which the decision is based," as required by statute.
2. The investigator drafts the Initial Decision and cover letter to the manufacturer, for the AA's signature. The Initial Decision states that there is a safety related defect in vehicles or equipment and the basis therefor. The letter briefly summarizes the basis for the Initial Decision. It also specifies the time and place of the Public Meeting at which the manufacturer and other interested persons can present information, views, and arguments on the issue of whether a defect exists and/or whether the defect is related to motor vehicle safety. In addition, it sets a date by which written comments must be submitted, which is normally 30 working days after the Initial Decision.

3. The information on which the Initial Decision is based should be furnished to the manufacturer pursuant to 49 U.S.C. § 30118. Generally, the EA Action Report will be an enclosure to the decision letter. Depending on the size of the public file, either the entire file or an index to the file will also be enclosed.
4. The investigator drafts a notice to be published in the Federal Register. The notice:
 - a. Identifies the applicable motor vehicle or item of equipment and its manufacturer;
 - b. Summarizes the information upon which the Initial Decision is based;
 - c. Gives the location of the information available for public examination; and
 - d. States the time and place of the Public Meeting, the deadline for written submissions and the deadline for oral presentations at the meeting in which the manufacturer and interested persons may present information, views, and arguments concerning the Initial Decision.
5. The deadlines for the submission of information and the date of the Public Meeting can be extended at the discretion of the AA for Enforcement.
6. The Office of Chief Counsel must review and concur with both the initial decision and the Federal Register notice.
7. The investigator apprises the Office of Communications and Consumer Information of the Initial Decision and time and place for the public meeting well in advance of the public announcement.
8. The investigator is primarily responsible for organizing the Public Meeting. This includes, e.g., reserving an appropriate meeting room, obtaining sign language interpreters, assuring that a court reporter is present, drafting a news release to further notify the public of the Meeting, inviting participants (including consumer complainants and experts), confirming participation (including travel and lodging for invited participants), obtaining exhibits (such as failed parts, displays, and photographs), preparing an agenda, and preparing an opening statement for the presiding official. Normally, an attorney from the Litigation Division of the Office of Chief Counsel assists in these tasks.
9. The Public Meeting is an informal proceeding at which manufacturers and interested members of the public may make oral presentations of information, views, and arguments with respect to the Initial Decision. Normally, the Associate Administrator for Enforcement presides at the Meeting, but in certain cases higher or lower ranking officials may preside. Other agency officials also participate, as appropriate. There is no formal examination or cross-examination of speakers, but agency officials may ask clarifying questions. A transcript of the Public Meeting is prepared and placed in the public file. Exhibits may be offered by the agency, the manufacturer, or members of the public.

5.0 FINAL DECISION

If the manufacturer continues to refuse to conduct a recall following the Public Meeting, the Administrator is briefed on the matter and is provided with the appropriate portions of the investigative record. This includes, at a minimum, the Engineering Action Report (which describes the basis for the Initial Decision), a summary of the written comments on the Initial Decision, and the transcript of the Public Meeting. In addition, on the relatively rare occasions

when ODI conducts further investigative activities after the Public Meeting (e.g., where issues raised at the Public Meeting require further exploration), the results of those activities are also provided. Supplemental investigative activities must be identified in the public file. Also, the manufacturer is given the opportunity to comment on the results of those activities.

If the Administrator concludes that the investigative record demonstrates that a safety-related defect exists, NCC prepares the Final Decision, with input from ODI. That decision document summarizes the basis for decision. In addition, the Administrator issues a formal order directing the manufacturer to furnish notification of the defect to owners, purchasers, and dealers and to provide a cost-free remedy as specified in 49 U.S.C. § 30118-30120.

If the Administrator does not conclude that the investigative record demonstrates that a safety-related defect exists, the investigation is closed and the manufacturer is notified of the closing in a letter signed by the Administrator. The investigator prepares a Closing Report that, after NCC review and approval, is placed in the public file. This report includes a statement of the reason(s) for the closing the investigation. A notice of the closing of the investigation is published in the Federal Register 49 CFR 554.11.