Safety Management System

ANPRM, 74 Fed. Reg. 36414 (July 23, 2009)
Comments on the Advanced Notice of Proposed Rulemaking
Submitted through the Federal eRulemaking Portal at http://www.regulations.gov

Submitted by the
Modification and Replacement Parts Association

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Docket Operations, M–30
U.S. Department of Transportation
1200 New Jersey Avenue, SE
West Building Ground Floor, Room W12–140
Washington, DC 20590

Dear Sir or Madam:

Please accept these comments on the ANPRM, which sought public comment on the idea of a Safety Management Systems (SMS) rule.

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Who is MARPA?

The Modification and Replacement Parts Association was founded to support PMA manufacturers and their customers. Aircraft parts are a vital sector of the aviation industry, and MARPA acts to represent the interests of the manufacturers of this vital resource before the FAA and other government agencies.

MARPA is a Washington, D.C.-based, non-profit association that supports its members' business efforts by promoting excellence in production standards for PMA parts. The Association represents its members before aviation policy makers, giving them a voice in Washington D.C. to prevent unnecessary or unfair regulatory burden while at the same time working with the FAA to help improve the aviation industry's already-impressive safety record.

MARPA represents a diverse group of interests – from the smallest companies to the largest - all dedicated to excellence in producing aircraft parts.

Summary of the Comments

MARPA applauds the FAA's efforts to continuously support safety. MARPA has found that many of the FAA's desired goals that are expressed as SMS elements are already part of the FAA's regulations that apply to PMA holders.

A Note on Citations

Unless otherwise noted, all citations to FAA regulations in Part 21 of Title 14 (i.e. 14 C.F.R. § 21.xxx) are to the regulations as amended by Production and Airworthiness Approvals, Part Marking, and Miscellaneous Amendments, 74 Fed. Reg. 53368 (October 16, 2009). In some cases, these are regulations that are not effective until April 14, 2010, but they should all be effective before the SMS rule is published.

Implementation Advice

Background

The FAA has requested comments on the Safety Management Systems rulemaking. This request was issued in the form of an ANPRM – Advance Notice of Proposed Rule Making – in the Federal Register.

MARPA has been working on the SMS project and is represented on the SMS Aviation Rulemaking Committee (ARC).

ICAO has published significant guidance on implementing SMS programs; so much guidance, though, that it must be reduced significantly to a level that will permit the publication of implementing reguations. In order to help the FAA make sense of what is necessary – and what is not necessary – within a SMS program, the FAA has issued the ANPRM in order to ask for industy's opinions about some of the core elements of SMS. A primary focus of this ANPRM is on collecting data about existing SMS programs, but it would also be important for companies to share information about non-SMS programs that meet the same objectives as SMS programs.

Continued Operational Safety Programs as a Model for SMS

The FAA released a recommended structure for a Continued Operational Safety (COS) program in one of its internal order (FAA Order 8110.42C) about a year ago – on June 23, 2008. Despite the fact that the program is only one year old, and the FAA has not been able to budget any resources to active promotion of COS, several MARPA members have nonetheless implemented COS programs that permit safety data collection and risk-based analysis of that data.

At present, COS is still in its infancy, and it has mostly been adopted by the largest PMA companies and companies working on complex and critical parts. COS has always been viewed as providing the infrastructure to support a SMS program – so MARPA member data and information about their implementation of COS programs would be very useful to the FAA.

No regulation requires a COS program, it is only a recommendation; but those PMA companies that have implemented COS programs have done so vigorously and voluntarily. The popularity of COS as a mechanism for managing safety is growing. Last year, after the COS guidance was issued by the FAA, MARPA hosted a training session on how to implement a COS program and 60 people from PMA companies attended.

COS, which is currently a voluntary program, could serve as a model for the implementation of SMS. Its popularity has continued to grow. MARPA has made a commitment to expand its COS Committee and to task them to promote COS as a model for safety management. A public-private partnership promoting safety management systems like COS and SMS could be very effective in delivering industry acceptance. A good example of past FAA-industry cooperation to promote a voluntary program is the promotion of FAA AC 00-56 (Voluntary Industry Distributor Accreditation Program), which has been

successful in being adopted and accepted, and has also been successful in having a positive affect on safety.

We believe that a voluntary implementation of COS systems, designed to utilize the existing regulatory structure as a framework for the implementation of safety management systems, would be an effective mechanism for implementation of SMS.

How Do the Current Manufacturing Rules Address the SMS Elements?

The FAA and ICAO describe SMS as containing four key elements: Safety Policy, Safety Risk Management (SRM), Safety Assurance (SA), and Safety Promotion. Each of these four is addressed, to a lesser or greater degree, in the existing regulations

Safety Policy

Safety policy outlines the methods and processes the organization's SMS will use to achieve the desired safety outcomes. Under existing regulations, manufacturers are already required to outline the methods and processes they use to achieve the desired safety outcomes.

Aircraft and aircraft parts manufacturers produce their parts in accordance with approved designs. The manufacturer must demonstrate compliance with all applicable safety regulations as a condition of obtaining design approval. 14 C.F.R. §§ 21.20, 21.303.

The FAA has explained that a safety policy establishes the organization's commitment to incorporate safety in all aspects of its business. Production approval holders are required to establish quality manuals that explain the organization's quality system. 14 C.F.R. §§ 21.138, 21.308.

Perhaps the most important regulation, from the point of view of implementing a Safety Policy, is the requirement to have a quality system that ensures compliance to the approved design. 14 C.F.R. §§ 21.137, 21.307.

Each production certificate holder must also provide the FAA with a document describing how its organization will ensure compliance with the provisions of the production approval regulations. 14 C.F.R. §§ 21.135, 21.305. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

The FAA has also suggested that a safety policy should also show how an organization will continually improve safety in all aspects of the business. While continuous improvement is a laudable goal – a goal that MARPA encourages – continuous improvement within the organization cannot be imposed by regulation without establishing a continuously shifting set of objective standards. Such continuously changing objective standards would violate basic principles of equal protection (all companies must be subject to the same regulatory standards) and due process (regulatory standards must be promulgated through due process, as described in the Administrative Procedures Act).

While continuous improvement may not be within the reasonable scope of objective regulations, it is a goal that is often adopted voluntarily through existing quality management systems. In particular, continuous improvement is an element of the existing Continued Operational Safety program published by MARPA (further discussed *infra*, in Safety Risk Management).

Thus, all of the elements of a Safety Policy seem to exist in the existing manufacturing regulations.

Safety Risk Management

The FAA has explained that Safety Risk Management (SRM) processes are used to assess system design and verify that the system adequately controls risk.

This is found in the regulations through a requirement to submit the design to the FAA for approval. E.g. 14 C.F.R. §§ 21.15 et seq. The design must meet the appropriate airworthiness standards of the regulations. 14 C.F.R. § 21.17 (cross referencing the airworthiness standards of Part 23-36 of the aviation regulations), 21.303. Where there is a common safety risk that must be managed at the initial certification phase, it must be managed in a uniform manner in order to avoid offending the equal protection clause of the Constitution, so it would not be appropriate to use SRM to impose safety standards on some companies and not on others – instead, the FAA currently uses the required reporting structure () to collect data and to promulgate regulations that impose new safety standards to address issues not previously addressed by the airworthiness standards. In-service issues are addressed through mechanism described in the Safety Assurance portion of this discussion.

Safety risk management is also intrinsic in the requirements that require a production approval applicant to submit the quality system to FAA review and approval. E.g. 14 C.F.R. §§ 21.135, 21.138, 21.305, 21.308.

Under current regulations, when safety risks are identified during certification, they must be mitigated or the applicant will not receive design/production approval. There are a variety of regulations that require an applicant to engage in safety risk analysis and mitigation, such as:

- 14 C.F.R. § 25.343(b)(2) Design fuel and oil loads (requiring fatigue analysis to take fuel loads into account, from empty to full);
- 14 C.F.R. § 25.571 Damage tolerance and fatigue evaluation of structure;
- 14 C.F.R. § 25.907 Propeller vibration and fatigue;
- 14 C.F.R. § 25.1435(a)(4-5) Hydraulic systems (requiring fatigue effects of all cyclic pressures as well as prediction of performance under environmental conditions).

This is just a short list of examples, limited only to the transport category airframe rules, and is not meant to reflect a complete list of the airworthiness standards intended to predict and mitigate risk.

The FAA has explained that a formal SRM process should identify hazards, analyze those hazards to identify risk, and establishes controls to manage those risks. While the existing FAA system does this based on existing airworthiness regulations, the MARPA COS system also includes additional proactive / preventive efforts to identify risk, like:

- Examination of field experience for the part;
- A design review and safety analysis process;
- Study of existing literature, including instructions for continued airworthiness (ICA).
- A safety assessment of PMA candidate parts.

These elements of the MARPA COS may be thought of as PMA-specific elements that would be difficult for the FAA to regulate, but that may be adopted voluntarily by companies within their own Safety Risk Management Programs.

Safety Assurance

Safety Assurance (SA) processes are used to ensure risk controls developed under SRM achieve their intended objectives throughout the life cycle of a system. This includes information acquisition and analysis to identify additional risks not identified during the SRM process, as well as a mechanism for developing and implementing corrective action.

The existing regulations have a mechanism for reporting service difficulties to the FAA. 14 C.F.R. § 21.3. They also have requirement for design approval holders to remedy safety issues. 14 C.F.R. § 21.99.

The MARPA COS system also includes proactive efforts to identify risk, like:

- A closed loop system that requires a resolution to all field inquiries;
- Part-specific performance data trend analysis to assess part performance relative to the design assumptions;
- Part delivery statistics;

- Continuing review of TC holder maintenance instructions, and defined steps for addressing ICA revision that may have an affect on a part.

The specific implementation of each of these varies depending on the nature of the part in question. It would be difficult for the FAA to regulate these elements, because it would be difficult to set objective standards at a regulatory level. For example, how could a company prove to the FAA that a field issue was closed out satisfactorily? In cases where companies have attempted to involve the FAA in closing out reports based on field experiences, FAA inspectors who were unwilling to accept a closure have proven to be obstacles to smooth operation and closure, despite the fact that the field experience might have nothing to do with parts safety (like dissatisfaction with a part that was ordered incorrectly). This could result in FAA inspectors 'running the business' in areas that have nothing to do with safety – an unwanted occurrence when the FAA is already complaining that it does not have enough employees to accomplish the safety goals before it.

The MARPA COS system also includes additional steps to enable problem response, like:

- Developing a Safety Board that serves as a resource;
- Establishment of a response team whose mission is to evaluate field issues: facilitating investigation and also providing resolution;
- Coordination with FAA on response;
- Communication plans for working with both the supply chain and the customers;
- Customer notification system;
- Development and dissemination of detailed technical instructions for addressing identified issues;
- Using the company's Safety Board to direct development and implementation of the corrective action plan;
- Metrics for measuring effectiveness of a corrective action plan;
- Feedback for improving the preventative systems and procedures.

These represent a mechanism for achieving the requirements of 14 C.F.R. § 21.99. It works for many PMA holders but it is not the only way to achieve compliance with 14 C.F.R. § 21.99 and for that reason it would be inappropriate for the FAA to regulate such a mechanism.

Safety Promotion

The FAA has stated that Safety promotion requires creating an environment where safety objectives can be achieved, by encouraging a positive safety culture.

The FAA has described a positive safety culture as one in which there is an adequate knowledge base, competency, implementation tools, effective communications, ongoing training, and information sharing. Currently, the FAA's manufacturing regulations are focused on the airworthiness of the product, rather than the knowledge, training and competency of the staff. This could represent an area where additional FAA regulations to more actively promote a safety culture in the aerospace manufacturing could be necessary to meet the ICAO recommendations; however, one must question whether there is a positive cost-benefit balance in requiring ongoing training in a manufacturing environment in which (1) the manufacturing processes are 'frozen' to the scope of the FAA approval and (2) employee safety issues are already subject to OSHA training regulations.

MARPA believes that safety promotion is accomplished under the current regulations by the requirements to establish and follow a quality system. E.g. 14 C.F.R. §§ 21.135, 21.138, 21.305, 21.308.

Another element of safety promotion would be the ability of an SMS to interface with the SMS systems of other product/service providers, as well as with the regulator. Such interfacing allows product/service providers to address issues of mutual concern and allows the regulator to evaluate the performance of the product/service provider's SMS.

While the FAA is able to interface with company data collection through the required reporting mechanisms (e.g. 14 C.F.R. §§ 21.3), there is limited ability for companies to share safety data – particularly for competitors to share safety data.

We concur that this is an area where there is a need for greater involvement by the FAA, and for potential regulation. There are clear examples of safety occurrences that could have been avoided through better sharing of data.

One example was the incident in which an Extex compressor adaptor coupling failed, resulting in an accident. The FAA investigation showed that there had been eight previous accidents involving the same RRC 250-B and 250-C series engines with Rolls Royce compressor adaptor couplings. The investigation showed that the PMA part design and functionality was identical to that of the Rolls Royce corollary part, and that it was failing in the same way. If the prior Rolls Royce compressor adaptor coupling failures had been made public, then Extex would have had notice of an issue to be investigated in their own part design (and Extex's President, Larry Shiembob, has publically stated that his company **would** have engaged in an investigation of their own part if they had known that the Rolls Royce compressor adaptor couplings had been failing). The failures ultimately led to an Airworthiness Directive. Airworthiness Directives; Rolls-Royce Corporation 250-B and 250-C Series Turboprop and Turboshaft Engines, 70 Fed. Reg 261 (January 4, 2005).

MARPA recommends that the FAA make all of its occurrence databases available to all certificate holders, and explore mechanisms for sharing sensitive data in a manner that provides a positive enhancement to safety without causing competitive disadvantage to any parties.

Conclusion

Much of what is deemed essential to a SMS program is already in the existing regulations. The extent to which the rules fall short of the SMS ideal may be defined in areas where the FAA desires regulatory redundancy, and/or desires to establish shifting (continuous improvement) standards. Shifting standards fail to establish the sort of objective standards that are the hallmark of American jurisprudence and would be forbidden as enforcement standards.

However, companies are permitted to strive towards excellence beyond the standards found in the regulations in a non-regulatory regime. For this reason, we believe that the FAA can best meet the goal of establishing continuous improvement standards by establishing a voluntary compliance mechanism that encourages continuous improvement. This would be consistent with ICAO recommendations, which suggest that SMS be constructed within a non-punitive (non-enforcement) regime.

We appreciate your consideration of these comments.

Respectfully Submitted,

Jason Dickstein
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Modification and Replacement Parts Association