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Comments by Paul W. Rankin, President
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To

Pipeline and Hazardous Materials Safety Administration

Re: Docket No. PHMSA-2011-0283

“Hazardous Materials: Special Permit and Approval Applicant
Fitness Determinations”

February 29, 2012

Good afternoon. I am Paul W. Rankin, President, Reusable Industrial Packaging Association (RIPA). Approximately 20 members of my association have applications for Approvals awaiting action by PHMSA. These applications involve the use of ultrasound to detect leaks in new or reconditioned drums.

The purpose of my testimony today is to provide constructive comments on the PHMSA Approval process, and to ask the Agency to consider revising the “Approvals Standard Operating Procedures” (SOP) to account for unique issues related to the issuance of Approvals for new technologies. It is important to note at the outset that RIPA has experience only with the “general approvals” category.

(1) Completeness Review. Phase I of the Approval application process is a procedural review to ensure an application contains all the information required under the Hazardous Materials Regulations (HMR). Apparently, applications filed on-line are simply kicked-out of the system until they are administratively complete. Written applications, however, are reviewed and if found to be incomplete, formally “denied” or “rejected” by letter. An Approval application can be rejected or denied for even a single, minor administrative error. Unfortunately, unless the rejection letter points out each actual or perceived shortcoming in an application (there could be one or many minor or major problems), the process of application and denial could extend for months, or even longer.

To improve this process, RIPA suggests the following:

(A) DOT should adopt a procedure that requires the Project Officer charged with reviewing a written Approval application to (i) review the entire application, and (ii) advise the applicant in writing of any technical or administrative errors that have been identified.

(B) DOT should put in place a procedure to ensure that Approval applications that have been rejected for non-safety related reasons receive expedited review if they are revised and re-submitted within a reasonable time frame.

(2) Tier 1 review – General Approvals Category. Approval applications from RIPA members involve packaging and packaging testing and, therefore, are most likely evaluated under the General Approvals Approval Category. This category uses information from the HazMat Intelligence Portal (HIP), FMCSA’s SAFER system and other available information. The Project Officer also uses the “General Approvals and International Approvals Fitness Evaluation Form for New Approvals Applications or to Modify an Existing Approval.”

We have three concerns with the Tier 1 review process.

(A) To the best of our knowledge, data from the HazMat Intelligence Portal (HIP) is not available to the public. Until such data is available and subject to review, we urge OHMS to remove this criterion from the SOP or at least make it crystal clear which HIP criteria are being used by PHMSA.

(B) The other data used in a fitness evaluation, while publicly available, is simply a series of data points until such time as OHMS provides clear guidance to the public regarding the manner by which the data will be applied to applications. DOT must offer clear guidance on this important matter.

(C) The SOP states, "If the Applicant does not meet any of the criteria listed on the form (i.e. General Approvals Fitness Evaluation Form), then the Project Officer refers the Applicant to Field Operations..." for a Tier II fitness review. This negative wording implies that if the applicant is in perfect administrative compliance, his application is referred for a Tier II review. RIPA suggests that this wording be revised to say that if an Applicant "does" meet any of the criteria in the Form, the application will be sent out for a Tier II review.

(3) Tier II Review. According to the SOP, if a Project Officer refers an Approval application for a Tier II review, Field Operations staff must review the Applicant's written information and can ask for additional information. After this paperwork exercise is completed, Field Operations decides if the Applicant is "fit" or in need of an on-site inspection.

Apparently, Field Operations staff is simply reviewing for a second time the same information that was or should have been available to the Project Officer. This is clearly a redundant process and, worse, may be problematic since there is no guarantee that Field Operations staff has the requisite engineering or related expertise needed to properly assess all technical aspects of a given application.

The problems associated with a redundant application review process expand exponentially if Field Operations staff obtains additional information from an applicant, which they are authorized to do. At this point in the process, Field Operations staff is in possession of information they believe to be germane to an application that was not available to the Project Officer. What happens next? Does the information have to be provided to the Project Officer? What if the Project Officer and Field Operations staff do not agree that the information is germane to the application?

To avoid these problems, RIPA strongly suggests the SOP be revised to eliminate the Tier II paperwork review requirements granted to Field Operations staff, and empower the Project Officer to determine if applications found technically sound require a site visit. Applications that do require a site visit should be referred directly to Tier III for an inspection. This change will eliminate significant amounts of paperwork and delay and will have the added benefit of making the Project Officer responsible for ensuring that site visits are made only after an application has been found to be technically and administratively sound.

(4) Tier III Fitness Review. A Tier III fitness review is an on-site inspection by Field Operations staff. The criteria used for the visit are found in Appendix D of the SOP.

RIPA believes the “criteria” in Appendix D are presented in an extremely confusing manner and should be rationalized. Nearly all the “Inspection Criteria” constitute a decision tree that Field Operations staff must apply to determine if an on-site inspection is called for. For example, there are six criteria that if met indicate the need for a mandatory inspection, and four criteria that indicate a site inspection is unnecessary. Presumably, if an application has been found by the Project Officer to be technically and administratively complete, the only reason it would be elevated to Tier II or III is for the purpose of a site visit. If the Project Officer knows in advance that the application meets one or more of the “inspection deemed unnecessary” criteria, then the referral to Field Operations staff is a waste of time.

Assuming a site inspection is necessary, the SOP offers six criteria which, if met, would result in an Applicant being labeled “unfit”, and five criteria that, if met, would result in an Applicant being labeled “capable but not compliant.”

- (a) Three of the mandatory “unfit” criteria are:
 - (i) Failure to comply with terms of the approval,
 - (ii) Failure “to have required equipment to comply with the terms of the approval,” and
 - (iii) Failure to have quality assurance measures in place to ensure equipment is operating as designed.

RIPA believes that the first of these three criteria (i.e. “Failure to comply with the terms of the approval”) must be eliminated. It is impossible for an Applicant to comply with the terms of an approval that has not yet been written.

The second criteria (i.e. “Failure to have required equipment to comply with the terms of the approval”) is similarly problematic since it requires an Applicant to have foreknowledge of the terms of a yet to be written approval.

The third of these criteria (i.e. “Failure to have quality assurance measures in place to ensure equipment is operating as designed”) is odd because it leaves to the whim of a Field Inspector a key decision about operational practice. If, for example, a company has quality assurance measures in place at the time of inspection, but the Field Inspector deems these measures to be inadequate – based upon no written criteria – the SOP stipulates that the application must be denied. This seems to be a harsh outcome for a company that clearly has made an effort to operate in a safe manner and whose application has already been found to be in order.

RIPA also wonders what the term “capable but not compliant” means in practice. It appears to us that this term simply means the applicant is not fit. If an applicant is found to be “capable but not compliant” is the Approval granted or denied? What happens to the application at this point in the process?

This brings me to the issue of Approvals for new technologies. Under the current system, a company must purchase, install and make operational a new technology *before* applying for an approval. Indeed, the second criteria described above states that an applicant will be recommended “unfit” if he or she does not have the required equipment in place to comply with the terms of the approval.

This procedure forces companies to invest potentially large sums of money to install new technology without any assurance that they will receive an approval to operate that new technology. This high-risk, no reward option will clearly dampen, not encourage, investments in new technologies. Moreover, the process is counter to the manner in which most new technologies are developed and subsequently disseminated across an industry. (Note: Proprietary technology specifically designed for one plant or one company must be handled differently than technology that is likely to be used by an entire industry.)

In our case, an innovative machine manufacturer took a relatively common industrial technology (i.e. ultrasound) and devised a new application for the testing of industrial packagings. Several non-production pilot projects were built and successfully tested. However, the machines were (and are) relatively expensive items for companies in the container manufacturing and reconditioning industry. When RIPA members applied for an Approval, they were caught in the “Catch-22” I described earlier. They were advised that before an approval could be granted, they had to undergo a site visit during which time the efficacy of the tester would be evaluated. Obviously, this meant that a company had to buy the machine and get it up and running before being considered for an approval.

Given the fact that PHMSA has no objective criteria by which to evaluate an approval application, and that even a technically complete application can be overturned by Field Operations staff – also operating with no objective criteria - when asked by members if applying for an Approval for the new technology was wise, I had to advise them that this process was by nature subjective and may not be a constructive way to invest company money.

Luckily, one RIPA member threw caution to the wind and purchased a tester. Eventually, the firm was granted an approval, but we learned along the way that the approval process must be revised to promote rather than hinder the development and use of new technologies.

To this end, we recommend the SOP be amended to permit advanced approval of a generic technology, so that applicants who wish to use the technology must only demonstrate that they can effectively use the technology in a plant setting and abide by standard management, operational and quality assurance procedures that have already been broadly accepted by the Agency.

I thank PHMSA for this opportunity to provide comments on the Approvals process, and would be pleased to provide additional information at your request.