

“deployed,” should not prevent such protections from applying to any deployment of such technology that occurs on or after the effective date of the applicable Designation or Certification in defense against, response to, or recovery from any act of terrorism.

Termination of a Designation Resulting From Significant Modification

Several comments expressed concern regarding Section 25.5(i) of the proposed rule, which provided for automatic termination if a designated technology is significantly modified or changed as defined in that provision. The concern was essentially that the standard for termination is too vague, although at least one commenter opposed automatic termination for any reason.

It is vital that the Department be able to ensure that technologies for which protections are granted are not changed in a way that will significantly affect their safety or effectiveness. The Department does not have the ability to monitor every change to a designated technology, however, and therefore the interim rule must place the burden on Sellers to submit proposed changes to the Department so that they may be properly evaluated.

That said, the Department agrees with one of the comments that suggested that only changes that significantly reduce the safety or effectiveness of the technology should be subject to automatic termination, and Section 25.5(i) of the interim rule has been revised accordingly. In addition, that Section has been revised to authorize the Under Secretary, in lieu of issuing a modified Designation, to issue a certificate to a Seller that certifies that a proposed change or modification to a technology does not significantly reduce its safety or effectiveness and reaffirms the applicability of the existing Designation to the technology. That option should enable the Under Secretary to respond swiftly to submissions of relatively minor changes. The Department strongly encourages holders of Designations to submit to the Under Secretary any proposed modifications or changes that could significantly reduce the safety or effectiveness of the designated technology.

One commenter wondered how the Department will evaluate a proposed change in advance when the factors to be evaluated would seem to require actual “implementation” of the change. The Department is confident that Sellers will have effective methods to evaluate the safety and effectiveness of changes

to their technologies prior to actual commercialization, and the Department will take advantage of those same methods in its evaluation.

Confidentiality of Information

Seventeen commenters indicated a concern regarding the Department’s ability to protect the confidentiality of information that is provided in an application. In particular, there is apprehension that the Freedom of Information Act (FOIA) protections might be inadequate to guarantee nondisclosure of an applicant’s trade secrets or confidential business information. It was suggested that explicit protections similar to those available for source selection or procurement information under FAR section 3, or a declaration that all financial information provided is deemed voluntary, or both, be included in the interim rule.

The Department is committed to the protection of applicants’ proprietary information to the fullest extent required or permitted by law. Although the interim rule does not establish any new special protections (such as those in section 3 of the FAR), there are multiple protections available for applicants’ sensitive information. Those protections include the Trade Secrets Act (18 U.S.C. 1905), Exemption 1 (“national security”) of FOIA, and Exemption 4 (“privileged or confidential information”) of FOIA. In particular, Federal employees are subject to criminal penalties for unauthorized disclosure of information qualifying under Exemption 4 of FOIA. All contractors or other agents of the Secretary will be required to enter into nondisclosure agreements, and each will be examined on an Application-by-Application basis for potential conflicts of interest, before being granted access to any confidential information provided by applicants.

Services as Distinguished From Products

Fourteen comments expressed concerns that the language in the proposed rule did not make clear how certain provisions of the SAFETY Act will apply to services, as opposed to physical products. The Department recognizes that the Act applies equally to product-based technologies and service-based technologies.

The Department will evaluate services and products using the same seven non-exclusive criteria set forth in Section 862(b) and the corresponding provision in the interim rule (§ 25.3(b)), as required by the Act. These criteria include “demonstrated substantial

utility and effectiveness” and “studies * * * to assess the capability of the technology to substantially reduce risks of harm.” Similarly, qualified Sellers of service-based technologies must satisfy the same post-Designation obligations as Sellers of products. These obligations include reporting insurance status, notifying the Secretary of any transfer or licensing of the designated technology, and applying for modification of a Designation prior to making any significant change to the designated technology. Appropriate revisions have been made to Section 25.5(i) and other provisions of the interim rule to clarify their applicability to services.

Transfer or licensing of Designations for products and, in particular, services may not be appropriate, since the identity and established expertise of the Seller is often be an integral basis for a Designation. That issue will be addressed in appropriate cases in individual Designations, as provided in Section 25.3(f) of the interim rule.

Determining the Required Amount of Insurance

A number of commenters discussed the potential difficulty of determining the amounts of insurance that must be carried to satisfy claims arising out of, relating to, or resulting from an act of terrorism with respect to which qualified anti-terrorism technologies have been deployed. Issues revolve around concern that most liability insurance is not purchased product-by-product, so that it might be difficult to estimate the “price distortion” caused by needing to insure a proposed new product or service. It was also suggested that there is a circular dependency between insurance costs and Designation: *i.e.*, the cost of insurance depends on the liability exposure, which depends on the content of the Designation (if any), which in turn depends on the cost of insurance. There was also concern expressed that insurance is not available at any price for certain technologies.

The Department is aware of the difficulties involved in quantifying the price impact of insuring (or self-insuring) against the specific potential liabilities addressed by the Act. The Department will rely on expert opinion and analysis in this area, as it will with technical determinations of safety and effectiveness. The Department will address the potential circularity issue by evaluating the need for SAFETY Act protections assuming the non-existence of such protections, and then setting the required amount of insurance by taking into account all relevant factors, including the cost and availability of