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Regulator proposes reducing requirements for radiation-emitting products

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In a welcome move, on 1 April 2019 the U.S. Food and Drug Administration (FDA) proposed reducing regulatory requirements for a number of radiation-emitting electronic products, including radiation-emitting medical devices.

The current radiological health provisions under 21 Code of Federal Regulations Subchapter J have largely been in place and intact for nearly 40 years, with FDA issuing only a limited number of guidance documents in that time to refine the agency's approach to implementing these provisions. In the proposed rule, FDA noted a desire to clarify and update the regulations to help impacted industries by reducing outdated and duplicative regulatory requirements and to identify better ways to protect the public against exposure to radiation-emitting electronic products. In discussing the evolution of the regulatory landscape around these products, FDA also pointed to more modern ways to ensure patient and consumer safety, including measures for accountability promulgated by external stakeholder groups, states, voluntary consensus standards, and national health care organizations.

Proposed changes

Records and reports

One of the most impactful proposed changes is a series of modifications to the reporting requirements for electronic products to focus on those products that pose the greatest risk, while reducing regulatory burden for manufacturers of lower risk products. FDA cited, as an example, that a product report for an ultrasound or X-ray system under the radiological health requirements is duplicative if the firm is also expected to submit a premarket 510(k) notice with the same, or more, information related to radiation safety features and performance.

The proposed reduction in reporting requirements would eliminate reporting requirements entirely under the electronic product regulations for certain television products, phototherapy products, T lamps, and acoustic products (such as ultrasonic therapy or diagnostic ultrasound products). Product report requirements, including initial product reports and annual reports, for certain imaging technology such as computer tomography (CT), X-ray systems, X-ray high-voltage generators, particular radiation products, and spot film devices, among others, would also be removed. For each of these products, however, reporting of electronic product defects would still be required.

FDA also proposed removing requirements for manufacturers to report new versions of products that do not involve changes in radiation emissions or performance standard requirements through quarterly updates to annual reports. Instead, FDA proposed that new models be addressed in annual reports.

Finally, FDA also proposed adjusting the reporting requirements for accidental radiation occurrences (AROs). Under the proposed rules, AROs would not need to be reported for each occurrence of an event, but rather on a quarterly basis, as long as no death or serious injury is associated with the event. Medical Device Reporting obligations, however, would continue to be in place for any medical device products.

Radiation protection recommendations

As currently written, 21 Code of Federal Regulations Part 1000 includes various recommendations for radiation protection, such as use of specific kinds of patient shielding, adoption of quality assurance programs, and recommendations that some exposures be performed only after careful consideration of potential implications.

Citing the evolution of the technology, as well as regulatory collaboration between FDA and states, other federal agencies, and professional organizations, FDA indicated that the agency now considers these recommendations to be obsolete in terms of addressing relevant aspects of radiation control. FDA is proposing repeal of these radiation protection recommendations while encouraging practitioners to review and apply the most current guidelines developed by professional societies, along with the use of medical device labeling to ensure radiation protection. FDA indicated, however, that the agency would continue to utilize its authority over medical device labeling and would continue to review device labeling for adequate instructions for use of products. FDA also indicated that the agency will continue to participate with stakeholders engaged in developing safety education and standards for patient care.

Diagnostic X-ray systems

FDA proposed removing requirements for submission of assembler reports of certified X-ray components. Diagnostic X-ray systems would continue to be subject to all other relevant requirements as medical device manufacturers.

Laser products

FDA proposed codifying and expanding its policy from Laser Notice No. 42 (issued in 1989) to reduce requirements for manufacturers of laser products that are incorporated into electronic products. Laser Notice No. 42 explains that FDA considers firms that incorporate unmodified, certified Class I laser products into another product to be distributors of laser products that are certified and reported by other manufacturers, provided that certain requirements are met:

- Neither performance nor intended use of the certified product is modified. Rather, only the original required manufacturer's certification and identification labels are concealed.
- Labeling requirements are met when the certified product is removed from the product into which it had been incorporated.
- Labeling requirements are met in any service configuration of the certified laser product.
- The original laser safety information is distributed with the final product.

FDA proposed that this policy treating such entities as distributors (and exempting them from performance standards requirements and submission of product reports) be expanded to include

all classes of certified and unmodified laser products not intended for use as a component or replacement that are incorporated into another product. The laser product performance standards would still not apply to manufacturers of uncertified laser products, which are intended to be used as a component or replacement in a finished electronic product that is then certified by the manufacturer.

FDA also proposed codifying that supplemental reports to address modifications to Class IIa, II, and IIIa laser products no longer be required, consistent with the agency's longstanding provisions in FDA's 1992 Laser Compliance Guide.

Ultrasonic therapy products

FDA proposed repeal of the performance standards specific to ultrasonic therapy products, which are intended to generate therapeutic deep heat within body tissues for the treatment of selected medical conditions.

FDA cited that the recognized International Electrotechnical Commission (IEC) standards for the products provide at least the same level of protection of the public health and safety from electronic radiation as FDA performance standards, thereby obviating the specific performance standard requirements for these products. FDA also noted that removing the performance standards would provide greater flexibility for changes in technology for ultrasonic therapy products, while FDA would continue to have appropriate and effective regulatory oversight over such products through other regulatory controls, including medical device premarket review, quality controls, surveillance, and recall authority.

Key takeaways

It has been some time since these regulations were revisited, and these proposed changes and the corresponding reduction in regulatory burden are likely to be viewed by some stakeholders as long overdue. Industry should keep in mind, however, that numerous reporting requirements for these products will remain in place both for electronic product manufacturers generally and medical device manufacturers and distributors of products for which both sets of requirements apply.

To identify other opportunities for reducing regulatory burdens and unnecessary or duplicative regulatory requirements, stakeholders can submit comments to FDA on the proposed rule through 1 July 2019 via Docket No. FDA-2018-N-3303.

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