

**Kansas Administrative Regulations
Economic Impact Statement
For the Kansas Division of the Budget**

Kansas Department of Health and Environment
Agency

Susan Vogel
Agency Contact

296-1291
Contact Phone Number

28-35-135a, 28-35-135c, 28-35-135f, 28-35-135i, 28-35-135l, 28-35-135m, 28-35-135n, 28-35-135o, 28-35-135s, 28-35-135u, 28-35-178a, 28-35-178i, 28-35-181d, 28-35-181j, 28-35-181m, 28-35-181r, 28-35-181u, 28-35-181v, 28-35-192e, 28-35-192f, 28-35-192h, 28-35-195a, 28-35-196a, 28-35-227c, 28-35-231c, 28-35-264, 28-35-282a, 28-35-291, 28-35-450, 28-35-500, 28-35-500a, 28-35-504, 28-35-504a, 28-35-505, 28-35-700

K.A.R. Number(s)

Submit a hard copy of the proposed rule(s) and regulation(s) and any external documents that the proposed rule(s) and regulation(s) would adopt, along with the following to: Division of the Budget
900 SW Jackson, Room 504-N
Topeka, KS 66612

I. Brief description of the proposed rule(s) and regulation(s).

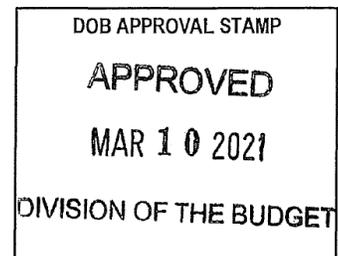
Pursuant to K.S.A. 48-1601 *et seq.*, the State of Kansas entered into an agreement with the Nuclear Regulatory Commission (NRC) in 1965 to regulate radioactive materials under the provisions of the federal Atomic Energy Act. Kansas has operated as an agreement state since that time. The regulated community in Kansas includes over 260 licensees across a variety of fields, from hospitals to manufacturing to research to the oil and gas industry. K.S.A. 48-1601 requires that the state provide for compatibility with the standards and regulatory programs of the federal government.

This regulation package includes provisions that make corrections to areas of non-compatibility identified by the NRC in current regulations and brings Kansas into compatibility with new federal requirements for medical use of radioisotopes. In this package, changes fall into five broad categories:

- 1) Several definitions have been created or slightly altered to maintain their original meaning and stay in harmony with other states as regulatory language evolves. Some wording has also been altered to make the regulations more readable and in keeping with current Kansas standards.
- 2) Updates were made to general licensure requirements to bring these requirements in line with federal standards.
- 3) Kansas has been granted authority by the NRC to review sealed source designs and the state required additional regulations to govern that project.
- 4) Transportation requirements were updated to match with modern interstate requirements.
- 5) Alterations were made to medical requirements to remain compatible with new NRC regulatory requirements.

The general license requirements cover an update to federal requirements for static elimination devices and ion-generating tubes, products containing tritium, krypton-85 and promethium-147. They also cover updates for luminous safety devices for aircraft, and federal testing requirements for products containing americium-241 or radium-226.

Medical requirements have been updated for ophthalmic physicists and associate radiation safety officers. Testing requirements have also been updated for technetium-99m generators that require elution.



X-ray regulations were also updated. Newly regulated modalities were included, such as e-brachytherapy, intensity modulated radiation therapy, radiation therapy simulation systems, and a forward-looking section on streamlining new uses in this rapidly evolving field. Additional minor changes were included, such as updating terminology and standardizing timeframes.

II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government. (If the approach is different, then include a statement of why the Kansas rule and regulation proposed is different)

Under the NRC-Kansas Agreement, the state of Kansas is required to have radioactive materials licensing which is compatible with the NRC. The amount of compatibility can vary by regulation, with some required to be essentially identical, some being a faithful interpretation, and some not required to be identical. These proposed amendments will enable the state to retain Agreement State authority by meeting the NRC requirement for compatibility. This approach is identical to the practice of contiguous states which have Agreement State status with the NRC (Note: Missouri is not an Agreement State and radioactive materials in Missouri are directly regulated by the NRC).

III. Agency analysis specifically addressing following:

A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

These regulations will enhance compatibility with neighboring states, encouraging growth of Kansan businesses and local offices of businesses from other states. Changes are minor and beneficial.

B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule and regulation and on the state economy as a whole;

Many definition changes will not add any cost to licensees, with some even reducing their operating cost. For example, allowing information to be passed to a tribal official's designee instead of the tribal official frees up valuable time for the official. Some of the new definitions are already in force in industry due to requirements by the NRC in the neighboring state of Missouri.

Regulations dealing with static elimination devices or ion generating tubes are geared towards their production, and have exceptions written in for products currently in use. Manufacturers must also use the national Sealed Source & Device Registry. No businesses manufacture them or other generally licensed products in the state of Kansas.

Radiopharmacies and hospitals would be affected by the new record-keeping and reporting requirements for Molybdenum-99 generators, but this is minimal. Tests are already conducted for each generator at regular intervals and after usage; the new requirements only need them to keep those records for three years and report failures. This may necessitate an additional drawer in a filing cabinet of good quality, or approximately \$30/licensee for a total of \$120.

No additional costs will be incurred for interstate transportation requirements, as any interstate shipper already applies those requirements. Fees may be incurred for sealed source or device registration, but those fees are already approved in the schedule of fees. The proposed regulations do not add any additional fees to the process.



C. Businesses that would be directly affected by the proposed rule and regulation;

The most directly affected businesses would be the four radiopharmacies in Kansas, although their costs would be minimal. No manufacturers of radioactive materials currently exist in Kansas, though these would be affected. These manufacturers would have slight increases in testing costs commensurate with increases in other states.

D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

Increased compatibility between Kansas and neighboring states encourages interstate commerce and attracts larger businesses to open Kansas branches. Better coordinated labeling for materials in interstate transportation increases safety and reduces overhead for companies that operate in both states. Higher testing costs, though they do impact the bottom line of manufacturing businesses, are essential for safety. If not implemented in a nationwide manner, higher safety protections in one state encourage businesses to move elsewhere and keep their workers and customers unsafe. The increase in costs is minimal. These costs also do not currently impact any manufacturer in Kansas and will not affect future businesses moving to Kansas due to nationwide implementation.

E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

Cost increases for this regulation are minimal to nonexistent for all licensees. Testing cost increases are no more than in all neighboring states.

F. An estimate, expressed as a total dollar figure, of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.

\$120.00

An estimate, expressed as a total dollar figure, of the total implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.

\$200.00 over five years (\$120.00 the first year for cabinets and then \$5/year/licensee for time spent filing).

Do the above total implementation and compliance costs exceed \$3.0 million over any two-year period?

YES NO

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

A majority of the proposed regulations do not deal with cost-incurring measures. Only one proposed regulation requires additional paper storage for tests run on eluted molybdenum-99 generators. The tests are already being run and only require a printout to be held for three years. The costs are based on the number of licensees that use generators and the average cost of limited, temporary file

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storage. Costs after purchasing a small file cabinet are limited to the time it takes to file.

Prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing if the total implementation and compliance costs exceed \$3.0 million over any two-year period to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.

YES NO

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.**

The proposed amended regulations do not change the revenues of cities, counties or school districts and do not impose functions or responsibilities to increase expenditures. However, when the notice of hearing for these regulations is published in the *Kansas Register*, standard agency procedure will be followed and the three organizations will be contacted electronically for comment with attached copies of the regulations, economic impact statement and published notice of hearing.

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).**

The agency posted an Information Notice on the KDHE/Radiation Control website, informing about the proposed regulation. The Information Notice referenced the contact person and number for comments or questions and that there will be a notification of a public hearing. The agency also sent out an e-mail to all licensees regarding the proposed regulations changes with the same information.

- I. For environmental rule(s) and regulation(s) describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).**

If not adopted, the state of Kansas could lose compatibility with the NRC, a federal agency. This would cause the NRC to revoke the state's capability to regulate radioactive materials and end the Agreement. This has been a source of income for the state, which would be lost in that event. If this should occur, regulatory oversight of radioactive materials in Kansas would revert to the NRC. In addition to the loss of oversight, the NRC charges much higher license fees than Kansas currently does.

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