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Bill Walker
FCML x74052, x74232 Mail SS-396

John Klucsik
ELD x27688 Mail MNBB-9604

The drafting committee considered regulation of the industry by performance standards. However, the regulation would have simply required that the licensee keep public and occupational exposure as low as reasonably achievable below the requirements of Part 20. Therefore the committee, in consultation with recognized experts in the field, decided which design standards would be critical elements in any licensee's plan to meet the ideal performance standard. Those critical elements are included in the proposed Part 35.

The GAO recommended that applicants submit procedures for review because the requirements of the extant Part 35 did not supply adequate safety guidance to the licensee. The drafting committee believes that the proposed Part 35 supplies that guidance. Therefore, it is no longer necessary to tie the licensee down to the procedures submitted with the application in order to establish a legal basis for enforcement actions.

The licensing role has, under the current Part 35, evolved into an enforcement tool. In fact, the license document serves only to legitimize the receipt and use of byproduct material. An on site inspector is the only individual who can determine whether material is being handled safely.

Norman McElroy
35970 3:30 4-14-83

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PDR PR
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Mtg. John Klucsik, Pat Vacca, Bill Walker,
Joe DeMedico, Debbie Bozik, Norman M'Elroy,
Vandy Miller

JK PV BW JD deb mlm Vandy
Note: 2pm 4-12 Tech Asst!

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JD: Paper doesn't address issues adequately. Ex BAS
audit. This isn't a mature industry, contrary
to what the experts say. Physicians won't
read P35, but their application is readable.
and includes 19, 20, 30, 71. NRC must
review credentials of physicians. Licensees
don't realize an inspection is an audit.
Major point: Appl provides site specific manual
of good practice.

PV: How do you deal with current licenses that
refer to current Part 35.

JK: Rule does not require or release need to submit
procedures. Says "NRC finds applicant 'committed'"
(p 35.28).

VM: we must nail down appl? before anything else.

BW: re podiatrists, dentists, we have added 35.950.

much conversation

BW: Summary: Joe thinks P35 should be more
specific in order to be enforceable.

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Inclusion of a 10.8 laundry list in proposed 35 would, contrary to Joe and Pat, not ensure safe use. It would simply pick up their veto. There are things in 10.8 that are not universally applicable. There are important "good practices" that do not appear in 10.8. We drafting committee felt that inclusion of the line by line specifics of 10.8 would unacceptably limit the discretionary powers of the RSO and ALC.

Examples

10.8 rec's that aren't universally applicable

1 R/L on survey instruments

don't need log-log paper for dose calibration linearity, which

sys shields may not be possible for chem therapy pts w/ bad veno

not just pediatric pts.

why a toilet for brachy pts?

time and distance for brachy visits are not "hard & fast"

or universally applicable; mR/hr dictated

things missing from 10.8

no scatter medium nearby when calibrating survey instruments

"deet source mR/hr" should be posted on instrument, not filled

need 2 pc gloves w/ hot lab, change outer pc ea 10 min (The breaking)

I patients should use urinals to avoid splashing

I pt techs & nurses should have 24 hr thyroid count

Conclusion: 10.8 is the world according to its authors, to many others.