NRC Reports on Misadministrations and Unannounced Safety Inspections

The US Nuclear Regulatory Commission (NRC) receives about 500 reports of diagnostic misadministration each year. Accounting for misadministrations that occur in Agreement States, which generally do not require misadministration reports, the agency projects that about 1,500 diagnostic misadministrations occur annually in the United States. From the NRC's estimate of 20 million *in vivo* diagnostic nuclear medicine procedures performed in this country each year, the agency calculates a 0.0001 rate of diagnostic misadministration.

Regarding NRC radiation safety requirements, the medical community generally shows a high rate of voluntary compliance. The frequency of noncompliance items, however, is unnecessarily high, and could be reduced by using some basic management and quality assurance tools.

Table 2. Types of Citations Issued

	Number[1]	Basis[2]	Projected Frequency[3]
No citation line items	289	640	.451
Radiation Safety Committee		563	
meet quarterly	48		.085
keep minutes, have certain members, and make an annual ALARA review	16		.028
Dose calibrator		640	
make a daily constancy check	63		.098
make a quarterly linearity check	74		.116
make an annual accuracy check	51		.080
make a geometry check once	23		.040
Sealed sources		640	
make a quarterly inventory	17		.027
make a biannual leak test	66		.103
Survey instruments		640	
have one on hand	10		.016
calibrate annually	61		.095
General safety measures		640	
don't eat, drink, or smoke in laboratory areas	15		.023
wear gloves and lab coats	12		.019
use syringe shields	7		.011
measure and record each dosage	6		.009
lock stored material or keep it under surveillance	26		.041
provide training to clinic and ancillary staff	49		.077
check eluates for Mo-99 breakthrough	9		.014
file reports[4]	12		.019
miscellany	6		.009
Unauthorized activities		640	
byproduct material	3		.005
areas of use	4		.006
amounts	6		.009
physician users	25		.039
forms of material	5		.008
locations of use	2		.003
Personnel monitoring		640	
keep dose records	18		.028
provide whole body monitors	12		.019
provide extremity monitors (rings)	29		.045
monitor hands for contamination	12		.019
measure worker thyroid burden after doing an iodine therapy	13	208	.062
report overexposures	3		.006
review worker dose records	1		.002
Surveys		640	
make daily closeout surveys of the clinic	82		.128
take action in case of high dose rates or levels of contamination	8		.012
validate the survey procedure[5]	33		.052

The agency has compiled and analyzed data, presented in the following tables, from radiation safety inspections and misadministration reports.

[The NRC has licensed about 33% of the nation's hospitals and 20% of the private practitioners who use by-product (or reactor-produced) materials; the Agreement States (see *Newsline*, Oct. 1985, p. 1114) have licensed about 66% of the US hospitals and 80% of the private practitioners

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Table 1. Number of Citations per Inspection

Number of line items	Hospitals Number	Hospitals Fraction*	Private Practitioners Number	Private Practitioners Fraction*
0	237	.45	45	.38
1	95	.18	20	.17
2	61	.12	15	.13
3	50	.10	16	.14
4	23	.04	11	.09
5	19	.04	3	.03
6	9	.02	5	.04
7	8	.02	2	.02
more	20	.04	1	.01

*Sum is not 1.00 due to rounding error

Table 2. Types of Citations Issued (cont.)

	Number[1]	Basis[2]	Projected Frequency[3]
Packages		640	
keep a record of receipts	6		.009
survey incoming packages	57		.089
document outgoing packages	12		.019
Xenon requirements		640	
measure and maintain room exhaust rates	11		.017
check xenon trap efficiency	8		.012
Implant therapy requirements		102	
survey the patient's room	10		.098
survey the patient and count the seeds to assure all have been removed	1		.010
make a quarterly inventory	3		.029
Radiopharmaceutical therapy requirements		180	
survey the patient's room	5		.028
collect and monitor waste from the room	1		.006
Waste disposal		640	
keep records	11		.017
hold decay-in-storage waste for ten half-lives	5		.008
monitor house waste collected in the clinic to assure it is "cold"	14		.022
don't discard "hot" waste in "cold" containers	8		.012
don't incinerate unless authorized	1		.002
miscellany	7		.011
Teletherapy requirements		102	
calibrate the unit annually	7		.069
spot check the unit monthly	10		.098
service the unit each five years	1		.010
qualified expert must review spot check	3		.029
calibrate dosimetry instrumentation	6		.059
install a room monitor	2		.020
leak test the unit each six months	6		.059
review the qualified expert's training and experience	2		.020
Posting		640	
post NRC Form 3, the license, etc.	16		.025
post rooms and label containers	9		.014

[1]This indicates the number of times the line item citation appeared in the sample. Note that a citation may be issued for failure to do a repetitive task a single time—it does not necessarily indicate habitual noncompliance on the part of the licensee.
[2]This represents the number of licensees within the sample that could have been cited for the line item. NRC has issued 300 licenses to private practitioners, and 2200 licenses to hospitals. All licensees practice diagnostic nuclear medicine; 700 hospital licensees also perform radiopharmaceutical therapy; 400 hospital licensees also perform implant therapy; 400 hospital licensees also perform teletherapy.
[3]This extrapolates the sample findings to all licensees who could be cited for the line item; it assumes that the sample represented a statistically "fair" sample of NRC's medical licensees.
[4]For example, misadministration reports or worker dose history reports.
[5]Some licensees record removable contamination survey results as "cpm" rather than "μCi/100 cm^2" or "dpm/100 cm^2."

Table 3. Types of Diagnostic Misadministrations

Type of Misadministration	Fraction of Reports
Wrong radiopharmaceutical administered	.74
Wrong dosage administered	.04
Radiopharmaceutical administered to wrong patient	.22
Radiopharmaceutical administered by wrong route	.00
Wrong byproduct material administered	.00

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who use byproduct materials.]

As part of its program to provide assurance of public health and safety in the use of reactor-produced radioactive materials, the NRC inspects medical licensees about once every three years, beginning promptly after the license is issued. Almost all inspections are unannounced.

Inspection of NRC Licensees

Table 1 shows the number of citations per inspection for hospitals and private practitioners for 1985. Table 2 outlines the citations and their frequencies.

Some of the citations, such as leak tests, training, and personnel monitoring, can be issued to any licensee; others, such as brachytherapy source counts or teletherapy calibrations, can only be issued against the licensees authorized for those clinical procedures.

Table 2, therefore, provides the *projected* noncompliance rates for all licensees that might receive each citation. The projections are based on an analysis of 640 inspections from 1985—about 66% of the medical inspections conducted that year.

"Forgetfulness" in Most Cases

It is fairly uncommon for an inspector to find someone who doesn't know how to perform certain basic radiation safety tasks, such as testing a dose calibrator for linearity or checking a sealed source for leakage. When workers do these tasks incorrectly, however, *the licensee*—not the employee—is responsible for the noncompliance item.

In most cases, it appears that items of noncompliance are caused by forgetfulness. Many noncompliance items could probably be eliminated by posting ticklers on equipment (i.e., "calibration next due on _____") and by establishing a perpetual calendar. This calendar could be used to schedule radiation safety committee meetings, equipment checks, sealed source inventories and leak tests, and continuing education sessions—assigning each activity to a specific week of the year.

For example, radiation safety committee meetings could be scheduled for the first weeks of February, May, August, and November; the xenon trap check could be conducted during the second week of each month, and so on.

More Unsettling Citations

The noncompliance rate for implant therapy room surveys and teletherapy spot checks is a bit more unsettling than the other citations. For situations where a more extensive radiation safety procedure is done on an occasional basis, a checklist for these tasks (similar to the preflight checklist used by an airplane pilot) would probably eliminate these items of noncompliance.

Many licensees try to correct the problem by revising the implant radiation safety procedure in the *Standard Procedures Manual.* Because the manual is often used primarily as a training tool for new employees, however, this solution is less likely to reduce the noncompliance rate.

Diagnostic Misadministrations

The NRC has analyzed diagnostic misadministrations by type (Table 3) and cause (Table 4). Although incomplete or unclear reports may have caused some error in the calcula-

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Table 4. Causes of Diagnostic Misadministration

Precipitating Event	Fraction* of Reports
Central nuclear pharmacy mislabeled a unit-dose syringe	.08
Central nuclear pharmacy mislabeled a multi-dose vial	.04
Clinic technician mislabeled a unit-dose syringe	.01
Clinic technician mislabeled a multi-dose vial	.12
Clinic technician misunderstood prescription	.04
Clinic technician drew dosage from wrong multi-dose vial	.22
Clinic technician did not use dose calibrator correctly	.00
Clinic receptionist misunderstood referring physician's request	.12
Ward nurse requested wrong clinical procedure	.05
Ward nurse requested clinical procedure for wrong patient	.06
Ward nurse brought wrong patient to clinic	.05
Wrong patient answered waiting room page	.06
Clinic technician selected wrong patient in ward or waiting room	.02
Clinic technician selected wrong syringe from dosage cart	.14

*Sum is not 1.00 due to rounding error

COMMENTARY

DOES MULTICOMPETENCY MEAN COMPETENCE?

The issue of "multicompetency" training for nuclear medicine technologists may not arouse concern among nuclear medicine physicians, technologists, and hospital administrators, but some disturbing trends have emerged that could affect everyone involved in nuclear medicine. The new breed of the "multicompetent" or "multiskilled" individual in allied health may well pose problems for technologists as well as their employers.

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Before discussing these potential problems, it is necessary to establish some precise definitions because these terms should not be used interchangeably. *Cross-training* occurs when an individual has training in more than one allied health discipline, as, for example, in nuclear medicine technology and radiography. The term does not distinguish whether this training is formal or "on-the-job." A *multicompetent* professional has acquired more than one competency that has been demonstrated through certification or licensure. Lastly, a *multiskilled* person may perform several jobs—such as taking an X-ray, drawing blood, performing simple laboratory procedures, and typing reports—but is not certified or licensed in any one area. Much of the recent confusion has resulted from an increased use of the term "multicompetent" to describe individuals who are actually "multiskilled," and from newly established educational programs that offer degrees in "multicompetency" although the graduates more closely fit the definition of "multiskilled."

The recent emphasis on multiskilled workers has developed in part from a reported "shortage of health technicians." (*1*) Others have rationalized that financial limitations on employers and the need in rural hospitals for allied health workers who are proficient in several areas result in a high demand for multiskilled personnel (*2*). The obvious short-term advantage for institutions employing multiskilled employees lies in paying one salary instead of two or three. One obvious disadvantage, however, is that hospitals and physicians are at greater risk of facing lawsuits when required procedures are not performed by competent technologists.

Some states require that certain tasks be performed by licensed individuals, and lawsuits could also develop when these rules are overlooked (*3*). Certified workers could eventually be displaced by multiskilled technicians, opening up the possibility of employee lawsuits against hospitals. The question of whether third-party payers will reimburse for procedures done by noncredentialed technicians has been investigated by the National Commission on Health Certifying Agencies, and the results are inconclusive (*4*). The Joint Commission on Accreditation of Hospitals may

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tions, the numbers reflect a fairly complete picture of the misadministration problem.

It appears that most misadministrations result from momentary distractions or miscommunications—human errors that occur despite adequate training and experience of the individuals involved and their observance of all safety measures. These human errors may be categorized in four groups.

- **Mislabeling** caused by selection of the wrong adhesive label, inadvertent selection of the wrong vial from stock, or inadvertent transposition of vials or syringes.
- **Miscommunication** caused by unclear or incorrect use of terminology intended to identify the desired clinical procedure or patient.
- **Patient misidentification** caused by common surnames, hearing difficulties, or failure to check identification bracelets.
- **Incorrect stock selection** caused by inattention to detail.

The process for ordering and performing nuclear medicine studies does not appear to be amenable to the kind of mechanical or electronic fail-safe measures used to prevent mistakes in manufacturing and other multi-step processes. Diagnostic misadministrations, however, occur quite infrequently.

[For a copy of the most recent complete analysis of misadministration reports, contact: Kathy Black, Office for Analysis and Evaluation of Operational Data, Nuclear Regulatory Commission, Washington, DC 20555.]

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