The Clean Air Act and Nuclear Medicine

Daniel F. Kane

Associates in Medical Physics, Cleveland, Ohio

This continuing education article explores an important aspect of regulatory compliance, the Clean Air Act, for nuclear medicine professionals. The author analyzes the evolution of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for radionuclide emissions, explains the rationale of the evaluation and offers a simple, yet comprehensive, methodology to demonstrate compliance with the EPA's radionuclide emission standards. Commentary is offered regarding the transfer of regulatory responsibility for these standards from the Environmental Protection Agency (EPA) to the Nuclear Regulatory Commission (NRC).

Key Words: Environmental Protection Agency; National Emission Standards for Hazardous Air Pollutants; radionuclide emissions

J Nucl Med Technol 1996; 24:3–9

In the U.S., the safe use of radionuclides is governed by the Nuclear Regulatory Commission (NRC) or an Agreement State. Until November 1992, the NRC had been the solitary regulator and inspector of radionuclide emissions to air from licensed facilities for the nuclear medicine community. Other interrelated agencies such as the Department of Transportation (DOT), the Occupational Health and Safety Administration (OSHA) and the Environmental Protection Agency (EPA), occasionally enter the regulatory environment of nuclear medicine in a limited fashion.

Although the EPA may appear to be a newcomer to the nuclear medicine arena, it has developed numerous regulations related to radioactive effluents for the nuclear power industry, has developed standards for radon and radionuclides in water, and advises the President regarding radiation matters that affect health.

Historically, the NRC and Agreement States have been the inspectors and enforcers for collateral agencies that have a regulatory interest in nuclear medicine. The clearest example of this the relationship is between the DOT and the NRC. Although the DOT has the authority to enforce its own regulations (and independently does so), the general responsibility for inspection and compliance has been assigned to the NRC or Agreement States.

The development of auxiliary regulations is the responsibility of the specialized regulatory body. The DOT develops regulations related to the transportation of all materials, including radioactive materials. The NRC and Agreement States incorporate these auxiliary regulations into their own and inspect and license accordingly. Rarely, if ever, are these collateral regulations in conflict or duplicative of existing NRC or Agreement State regulations.

In contrast to this historical mechanism of regulation, licensing, inspection and enforcement, the EPA has proposed and been forced by the courts to establish, as a rule applicable to all medical licensees, radionuclide emission standards that are not only duplicative but many times more restrictive than effluent standards recently published in 10 CFR 20, Appendix B (*1*).

The EPA regulation, 40 CFR Part 61, Subpart I, promulgates radionuclide air emission standards known as NESHAPs (National Emission Standards for Hazardous Air Pollutants) for radioactive effluents. These standards apply to most radioactive materials licensees, including all nuclear pharmacies, hospitals, radiopharmaceutical manufacturers, research facilities and clinics. There are exceptions to the requirements of Subpart I, but the only possible medical exemptions to the regulations are for low energy (less than 30 MeV) accelerators or cyclotrons.

Subpart I limits the radionuclide emissions to the ambient air from NRC- or Agreement State-licensed facilities to an amount that would not cause any member of the public to receive in any year an effective dose equivalent (EDE) in excess of 0.1 mSv (10 mrem); of which no more than 0.03 mSv (3 mrem) can be attributed to radioiodine. In the EPA's view this protects the public health to a lifetime maximum risk of about 1/10,000 for a fatal cancer.

This stands in stark contrast to the standards published by the NRC in 10 CFR 20 *Standards for Protection Against Radiation* which allows the public to receive up to 100 mrem annually. This apparent incompatibility is possible because the EPA, and not the NRC, has the responsibility to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal

For correspondence or reprints contact: Daniel F. Kane, Associates in Medical Physics, LLC, 1384 Old Virginia Ct., Marietta, GA 30067.

TABLE 1
Evolution of NESHAP for Radionuclides

Date	Action
December 1979	Radionuclides listed as Hazardous Air Pollutants under Section 112 of the Clean Air Act (CAA).
April 1983	EPA proposes to regulate radionuclide emissions in four of eleven categories including medical licensees.
February 1984	Sierra Club files suit to compel the EPA to take final action on radionuclide NESHAP.
October 1984	EPA withdraws proposed radionuclide emission standards for medical licensees.
December 1984	EPA found in contempt of court; ordered to promulgate final radionuclide standards. EPA again decides to regulate medical licensees.
July 1987	EPA loses lawsuit, Vinyl Chloride Decision, which requires two-step process to assess risk.
December 1989	EPA promulgates radionuclide NESHAP (40 CFR 61, Subpart I).
September 1990	Congress amends CAA, allows EPA to determine by rule, if NRC "provides ample margin of safety" to public health.
1990–1992	Numerous stays of Subpart I.
September 1992	EPA compelled by District of Columbia Court of Appeals to enact Subpart I.
November 1992	Final stay expires. Subpart I becomes effective for all NRC and Agreement State licensees.
January 1994	EPA publishes notice that confirms Subpart I is in effect (retroactive to January, 1993).
September 1995	EPA proposes to rescind 40 CFR Subpart I for NRC and Agreement State licensees request for comments.

Agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with the States." This authority stems from: Executive Order 10831; the Atomic Energy Act of 1954 as amended; and Reorganization Plan No. 3 of 1970 (*2*).

HISTORY

Even before the 1990 revision, the EPA's Clean Air Act (CAA) had been the subject of active litigation and assessment as it applied to the regulation of radionuclide emissions from medical licensees. Table 1 outlines the evolution of radionuclide NESHAPs. It was not the intention of the EPA to regulate radionuclide emissions. In October 1984, the EPA found that "control practices already in effect for those categories (NRC Licensees) protected the public with an ample margin of safety" (*3*) and withdrew the radionuclide NESHAPs.

The reinstatement of the radionuclide NESHAPs was the result of litigation filed in northern California, by the Environmental Defense Fund (EDF), Natural Resources Defense Council (NRDC) and the Sierra Club, protesting the withdrawal of the radionuclide NESHAPs and the decision not to regulate (*3*). Another critical legal decision occurred in July 1987 in *NRDC v. EPA*, known as Vinyl Chloride (*4*). This decision concluded that the EPA acted improperly when it considered the cost and technological feasibility of the standards without first determining the public health risk. This effectively reversed the October 1984 decision not to regulate and reinstated the radionuclide NESHAPs for NRC and Agreement State licensees, even though the lawsuit itself had nothing to do with radioactive materials.

On December 8, 1987, the EPA requested and received a voluntary remand of NESHAPs related to radionuclide emissions. The District of Columbia Court of Appeals granted this remand when the EPA agreed to reexamine all issues raised by litigation and take a "fresh look at the risks and issues involved in regulating or not regulating radionuclide emissions under Section 112 of the CAA" (*5*). This resulted in the publication of Proposed Rules (*5*) which appeared in the *Federal Register* on March 7, 1989. These proposed rules describe the basis of the NESHAP limits, the EPA's perspective on risk assessment, the legal framework of their decision and acceptable methods to demonstrate compliance. In December, 1989 40 CFR 61, Subpart I was published in final form (*6*). Following this publication, numerous stays were granted in an unsuccessful effort to halt the impending regulations while the EPA and NRC discussed and researched the transfer of responsibility to the NRC.

Congress acted in September 1990 and the CAA was revised. Part of this revision included a section addressing the issue of regulatory duplication between the EPA and NRC. Section 112 of the CAA reads in part:

> . . . no standard for radionuclide emissions from any category or subcategory of facilities licensed by the Nuclear Regulatory Commission (or an Agreement State) is required to be promulgated under Section 112 if the (EPA) Administrator determines by rule and after consultation with the Nuclear Regulatory Commission that the regulatory program established by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act for such category or subcategory provides an ample margin of safety to protect the public health (*7*).

Using the force of this law, the EPA issued a number of stays including one for a period of 18 mo. Finally, in *NRDC v. Reilly*, the District of Columbia Circuit Court (*8*) questioned the legality of further stays while the EPA studied the transfer of responsibility. As a result of this court decision, the EPA decided not to allow further stays and the final stay expired November 15, 1992.

The EPA then issued a notice in the *Federal Register* (*9*), on January 28, 1994, titled "National Emissions Standards of Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission (NRC) and Federal Facilities Not Operated by the Department of Energy (DOE)." This notice confirmed that 40 CFR Part 61, Subpart I is in force, effective November 15, 1992, for two categories of licensees: federal facilities not operated by the DOE and facilities licensed by the NRC or Agreement States. This latter category affects all medical use licensees including hospitals, clinics, nuclear pharmacies and radiopharmaceutical manufacturers. Reports to the EPA for the calendar year 1993 were due, if

TABLE 2
Comparison of Annualized Lifetime Risks of Death for Selected Activities

Hazard	Lifetime risk of death
Tripping and falling[1]	1×10^{-4}
Rabies[1]	1×10^{-7}
Driving to and from work[1]	1×10^{-4}
Working in government[2]	1×10^{-4}
Working in construction[2]	4×10^{-4}
Working in agriculture[2]	5.2×10^{-4}
Working in service industry[2]	6×10^{-5}
Working in manufacturing[2]	5×10^{-5}

[1]*Federal Register*. Vol. 54, No. 43; Washington, DC: General Services Administration; 1989.

[2]International Commission on Radiation Protection. *Limits for Intakes of Radionuclides by Workers*. ICRP Publication 30. New York, NY: ICRP; 1979.

TABLE 3
Regulatory and Advisory Agency Maximum EDE and Associated Lifetime Risk for Fatal Cancer in Unrestricted Populations

Regulatory agency	Maximum EDE (mSv)	Lifetime risk
NRC, Pre-1994[1]	5.0 (500 mrem)	1.5×10^{-2}
NRC, Current[2]	1.0 (100 mrem)	3.0×10^{-3}
ICRP, 1987[3]	1.0 (100 mrem)	3.0×10^{-3}
NCRP, 1987[4]	1.0 (100 mrem)	3.0×10^{-3}
NESHAP, 1994[3]	0.1 (10 mrem)	1.6×10^{-4}
Iodine NESHAP (1994)[3]	0.03 (3 mrem)	1.0×10^{-4}
Natural background, 1995[5]	3.0 (300 mrem)	9.0×10^{-3}
Negligible individual risk, 1987[4]	0.001 (1 mrem)	3.0×10^{-6}

[1]Code of Federal Regulations, Title 10, Part 20. Office of the Federal Register, National Archives and Records Service. Washington, DC: General Services Administration; April, 1992.

[2]Code of Federal Regulations, Title 10, Part 20. Office of the Federal Register, National Archives and Records Service. Washington, DC: General Services Administration; December, 1993.

[3]*Federal Register*, Vol. 54, No. 43; Washington, DC: General Services Administration; 1989; 9629.

[4]National Council on Radiation Protection. Report No. 91. Recommendations on limits for exposure to ionizing radiation. Washington, DC: US Government Printing Office; 1987.

[5]AAPM Report No. 53. Radiation information for hospital personnel. College Park, MD: AAPM; 1995.

necessary, by March 31, 1994 and annually by March 31 thereafter.

FACILITIES AFFECTED BY 40 CFR PART 61, SUBPART I

Every NRC and Agreement State Medical Licensee is affected by this regulation. This implicitly includes nuclear medicine clinics, hospitals, nuclear pharmacies, laboratories and radiopharmaceutical manufacturers. Specifically exempted from this rule are low-level radioactive waste facilities, low-energy accelerators (such as emissions from negative ion cyclotrons in PET centers, but not emissions incident to the manufacture or use of positron-labeled compounds), and facilities licensed to possess only sealed sources.

RISK ANALYSIS

The driving force of 40 CFR Part 61, Subpart I is the EPA's position that there is a strong basis for quantifying the risk of fatal cancers from radiation exposure. Other stochastic and nonstochastic effects were not considered because none pose, in the EPA rationale, a more severe risk to public health than fatal cancer. Further, the EPA feels that "fatal cancers occur much more frequently than nonfatal cancers and that cancers occur more often than genetic or developmental effects" (*7*).

The near concurrent publication of BEIR V (*10*), which re-evaluated the EDE received by the survivors of Hiroshima and Nagasaki and lowered the presumed dose received, most certainly influenced the EPA in lowering the acceptable level of risk. The EPA position is that there is no completely risk-free level of exposure to radiation for cancer (*11*). The risk model, as is typical for the regulatory community, is the linear, no-threshold model for biological effects.

In the Vinyl Chloride (*12*) decision, the level of risk to the public health that is acceptable or safe with respect to radionuclides in the air must be addressed in the reference frame of what is acceptable in the world in which we live. A summary of occupational risks are listed in Table 2. The current NESHAP limits the EDE to 0.1 mSv (10 mrem) per year to any member of the public and restricts the EDE contribution from all radioiodines to 0.03 mSv (3 mrem) to any individual per year (*13*).

In the EPA's estimation, these limits reflect a maximum lifetime risk of 1.6×10^{-4} (1.6 per 10,000 individuals) for a fatal cancer incident to radionuclide emissions. This is statistically predicted to cause 0.13 annual deaths within 80 km (51.2 mi) of an emission source. Since the total cancers may be nine times higher due to thyroid cancer (not considered to be fatal) the limit of 0.03 mSv has been proscribed for the sum of radioiodine emissions. This is reflective of an effort to limit the lifetime individual risk for fatal cancers related to radioiodines to 1.0×10^{-4} or 1/10,000 (*14*).

Table 3 lists the various EDE limits from a number of advisory agencies and the associated lifetime risks for a fatal cancer as calculated by the EPA risk model. Table 4 compares the NESHAPs for ^{133}Xe and ^{131}I (two potential effluents well-known to the nuclear medicine community) that are approximately one and three orders of magnitude more stringent than 10 CFR Part 20. This is reflective, in part, of the change in the maximum EDE allowed by regulation (10 mrem/yr for the EPA vs. 100 mrem/yr for the NRC). It is entirely possible that a licensee can be in full compliance with the applicable standard of 10 CFR 20 and simultaneously be in substantial violation of the CAA.

TABLE 4
Comparison of NESHAP and Part 20 Effluent Concentrations Limits for ^{133}Xe and ^{131}I ($\mu Ci/ml$)

Isotope	Part 20	ALARA level[1]	NESHAP	Exemption level[2]
^{133}Xe	5.0×10^{-7}	4.0×10^{-7}	6.2×10^{-8}	6.2×10^{-9}
^{131}I	2.0×10^{-10}	1.6×10^{-10}	2.1×10^{-13}	2.1×10^{-14}

[1]U.S. Nuclear Regulatory Commission. Regulatory guide 8.37. Washington, DC: NRC; July, 1993.
[2]Derived from 40 CFR 61.104(b) exemption limits.

As an example, a facility that uses ^{133}Xe generally has to demonstrate to the satisfaction of the licensing agency that their use of this gas will not cause an average effluent concentration in excess of 5.0×10^{-7}. This value is more than eight times the limit of 40 CFR 61. The only way most licensees can lower this potential effluent concentration is to increase the ventilation rate or decrease the administered dose by a factor of eight.

DEMONSTRATING COMPLIANCE

There are two levels of concern when analyzing effluent concentrations. First and foremost is compliance with the CAA, demonstrating that the sum of radionuclide effluents does not cause an individual to receive an EDE of 0.1 mSv (10 mrem). The second is to demonstrate exemption to reporting by showing and estimated EDE to the public of 0.01 mSv (1 mrem).

Licensees are required to demonstrate compliance at annual intervals based on the calendar year and file reports with the EPA, as necessary, on or before March 31st of the following year. Facilities emitting radionuclides in an amount of 10% or less of the dose standard (0.01 mSv EDE; 0.003 mSv from radioiodine) are exempt from filing a report with the EPA (*15*) (Table 5). Facilities shown not to be in compliance with the CAA NESHAPs are required to immediately institute remedial changes in operations to fall within the effluent standards and file monthly reports with the EPA until the EPA administrator determines that monthly reports are not necessary. It is in the licensee's best interest to demonstrate compliance at a level where they are exempt from reporting.

All radionuclides possessed by the licensee (except sealed sources and materials in unopened, non-leaking containers) are considered by the EPA to contribute to radionuclide emissions and must be considered. The physical state of the radionuclide is extremely important, but the chemical form is inconsequential to the evaluation. The amount of radioactive material allowed to be possessed under this regulation varies substantially by physical form with a factor of 1×10^6 difference between solid and gaseous forms, as shown in Table 6.

The EPA allows licensees to demonstrate compliance with a number of methods: annual possession limits; effluent concentration limits; or through the use of the EPA computer code COMPLY. Alternative computer models to determine compliance may be used if they meet certain criteria and are approved by the EPA. Records related to regulatory compliance must be maintained for a period of five years.

Since it is estimated that 98–99% of all medical licensees are in compliance with the NESHAP emission standards, alternative methods of compliance will not be explored here (*16*). The COMPLY program, which is available free from the EPA, consists of four levels of increasing complexity, known as Levels 1 through 4, and includes a catalog of approximately 400 isotopes (*17*).

ANNUAL POSSESSION LIMIT

COMPLY Level 1

The COMPLY program Level 1 is the annual possession limit method. The COMPLY program is not required to evaluate a licensee's compliance at this level. The average nuclear medicine facility can calculate compliance manually in a short period of time. The author's firm uses the form shown in Figure 1 to assist client facilities in manually demonstrating compliance using the Annual Possession Tables. The user need only list the amount of radionuclides possessed, divide by the annual possession limit and add the ratios together. The ratios represent the contribution of each radionuclide to the public EDE in mrem. By adding the ratios together, an estimated EDE from all radionuclides possessed is derived. To use the Annual Possession Limit method of COMPLY Level 1, two conditions must be met:

1. There must not be a receptor within 10 m of any release point, and
2. No milk, meat or vegetables can be produced within 100 m of any release point (*17*).

This level is extremely conservative. In estimating effluent it assumes 10% of the materials possessed are released as airborne effluent. If the sum of the ratios is 0.1 or less, including a maximum ratio sum of 0.03 for all radioiodines, the licensee is in compliance, exempt from reporting to the EPA and does not need to perform any further effluent analysis calculations. Even though it is extremely conservative in its estimates, our database of clients demonstrates that 81% of licensees successfully demonstrate compliance and exemption to reporting at this level.

CONCENTRATION TABLES

Use of the Concentration Tables requires either measured stack concentrations for all radionuclides used or EPA approval to measure air concentration at the nearest receptor. This may prove to be impractical for most medical licensees.

TABLE 5
Compliance and Reporting Thresholds for 40 CFR 61, Subpart I

Public EDE	Compliance	Exempt	Report required
Total EDE below 0.01 mSv (one mrem) with radioiodine contribution 0.003 mSv (0.3 mrem) or less.	Yes	Yes	No
Total EDE below 0.01 mSv (one mrem) with radioiodine contribution in excess of 0.003 mSv (0.3 mrem).	Yes	No	Annual[1]
Total EDE above 0.01 mSv (one mrem) with radioiodine contribution less than 0.003 mSv (0.3 mrem).	Yes	No	Annual[1]
Total EDE 0.1 mSv (10 mrem) or above without regard to radioiodine contribution to total EDE.	No	No	Monthly[2]
Total EDE of less than 0.1 mSv but radioiodine contribution greater than 0.03 (3 mrem).	No	No	Monthly[2]

[1]Facilities with EDE values between 0.01 and 0.1 mSv or radioiodine EDE values between 0.003 and 0.03 must file annual reports with the EPA administrator.

[2]Facilities with EDE values in excess of 0.1 mSv (10 mrem) or radioiodine EDE values in excess of 0.03 mSv (3 rem) must institute corrective actions and file monthly reports with the EPA administrator until the EPA administrator determines monthly reports are no longer necessary.

TABLE 6
List of Common Nuclear Medicine Radionuclides Possession Quantities (Ci/yr)[1]

Radionuclide	Gaseous[2]	Liquid[3]	Solid[4]
^{67}Ga	7.6×10^{-1}	7.6×10^{2}	7.6×10^{5}
^{123}I	4.9×10^{-1}	4.9×10^{2}	4.9×10^{5}
^{131}I	6.7×10^{-3}	6.7×10^{0}	6.7×10^{3}
^{111}In	4.9×10^{-2}	4.9×10^{1}	4.9×10^{4}
^{99}Mo	5.7×10^{-2}	5.7×10^{-1}	5.7×10^{4}
^{32}P	1.7×10^{-2}	1.7×10^{1}	1.7×10^{4}
^{82}Sr	1.9×10^{-3}	1.9×10^{0}	1.9×10^{3}
^{99m}Tc	1.4×10^{0}	1.4×10^{3}	1.4×10^{6}
^{201}Tl	1.8×10^{-1}	1.8×10^{2}	1.8×10^{5}
^{133}Xe	5.2×10^{1}	—	—

[1]From *A guide for determining compliance with the Clean Air Act standards for radionuclide emissions from NRC-licensed and non-DOE federal facilities, Revision 2*. Washington, DC: Environmental Protection Agency; 1989.

[2]Radionuclides boiling at 100°C or less or exposed to a temperature of 100°C or more must be considered to be a gas.

[3]Powders must be considered to be in liquid form.

[4]Mo-99 contained in a generator to produce ^{99m}Tc is assumed to be a solid.

If the data is available, as in the Annual Possession Limit methodology, the average annual concentration for every radionuclide used is divided by the concentration levels for environmental compliance (*17*). Again, if the sum of the ratios is 0.1 or less (including 0.03 for all radioiodines), the facility is in compliance and exempt.

COMPLY Level 2

Increasing in sophistication and decreasing in conservative assumptions, COMPLY Level 2 allows the user to adjust imputed data to reflect effluent controls and incorporate stack/vent characteristics, building size and source to receptor distance. In the event that actual concentration or release rates of radionuclides are not known, they can be estimated by multiplying the individual annual possession amounts by 1.0 for gases, 1×10^{-3} for liquids and powders and 1×10^{-6} for solids (*17*).

At this level, the use of xenon traps will allow the reduction of ^{133}Xe effluent by a factor of 0.1 (*17*). The estimation of concentrations coupled with the dilution by distance and exhaust rate generally will allow all but the largest of licensees with the highest volume of radioactive materials, such as universities and nuclear pharmacies, to demonstrate compliance, if not exemption from reporting, at this level.

Since the source-to-receptor distance is so critical in this calculation, it is important to define what is a source and what is a receptor. The source is the stack or vent emitting radionuclide effluents. There can be more than one stack emitting radionuclides and, if this is the case, all stacks will need to be considered. The COMPLY program will prompt the user as to the number of stacks involved.

The definition of receptor is derived from the Standard of 40 CFR 61.102 wherein "emissions of radionuclides, including iodine, to the air may not cause *any member of the public* to receive an effective dose equivalent of more than 10 mrem in any year, of which no more than 3 mrem may come from iodine" (emphasis added by author) (*18*). A member of the public is defined as a "person at the nearest residence, or off-site school or office (*18*). Licensees may consider the receptor to be the nearest off-site dwelling that is used at any time throughout the year. The distance from the source to the receptor is measured as the straight line distance (in meters) between the source and receptor (*19*). Offices that are part of the facility and under the control of the licensee are not receptors. The receptor can be on the same building if the nearest office, school, residence, etc. is not part of the same facility, as the case may be in medical office buildings not controlled by the licensee and commercial nuclear pharmacies housed in business parks where contiguous tenants share the same building. In these cases, the source and receptor are considered to be in the same building. Other on-site receptors would be residential activities such as nursing homes and dormitories. Patient rooms are not residences.

Using COMPLY Level 2, our database indicates that of the 19% of medical licensees required to file a report with the

FACILITY NAME: _____

LOCATION: _____

Date of Assessment: _____

Assessment Period (dates): _____

Nuclide	Annual Utilization[1] (Ci/yr)	Possession Limit (Ci/yr)	Ratios[2]
Ga-67		110	
I-123 (Capsules)		490000	
I-125		6.2	
I-131 (Capsules)		6700	
I-131 (Liquid)		6.7	
In-111		49	
Mo-99		57000	
P-32		17	
Sr-89		21	
Tc-99m		1400	
Tl-201		180	
Xe-133		52	
Other Radionuclides			
Other Radionuclides			
	All Radionuclide Ratio Totals		[3]
	Radioiodine (only) Ratio Totals		[3]

[1] Include amount on hand at beginning of period + annual utilization

[2] Ratios = $\frac{\text{Annual utilization}}{\text{Possession Limits}}$

[3] Contact *Associates In Medical Physics, LLC* if ratios exceed the following:
All Radionuclide Totals 0.1 *Radioiodine Only* Totals 0.03

FIGURE 1. Author's client compliance form.

EPA after COMPLY Level 1, 76% will now be exempt from reporting to the EPA. At Level 2 of the COMPLY program, 96% of our clients are exempt from reporting.

COMPLY Level 3

This level incorporates all of the information in Level 2 and factors in the distance from the facility and the nearest source of food production (farms). At Level 3 there are two kinds farms considered: those for vegetables and those for milk and meat. If the receptor can produce significant quantities of vegetables, meat or milk at home and the nearest receptor is a home, then the user must assume that the receptor actually does so. The fact that the receptor chooses not to produce a significant amount of food at home is immaterial. The words of the EPA regarding producing food at home are, "if he is able to do so, then it must be assumed that he does" (*19*). At Level 3, 99% of our client base was found to be in compliance and exempt from reporting.

COMPLY Level 4

This level expands the analysis of the potential effluent by the incorporation of a wind rose, uses more in-depth stack characteristics (building length, stack temperature, ambient air temperature), and factors in the distance to three types of farms: milk, meat, and vegetables. This significantly increases the sophistication of the analysis and may require outside consultation with sources such as meteorological data stations for wind conditions and chambers of commerce for the locations of various farms. The 1%–2% of users who must use this level to demonstrate compliance would be best served by carefully reviewing the *User's Guide for the COMPLY Code* (*19*), evaluating their handling techniques and considering effluent monitoring. Licensees may use increasing levels of analysis within the COMPLY program to demonstrate exemption to the reporting requirement even though they may be in compliance at a lower level. At this level, 100% of our client

base was found to be in compliance with the NESHAP standards and exempt from reporting.

DISCUSSION

The 40 CFR Part 61, Subpart I became effective for all NRC and Agreement State licensees on November 16, 1992. Facilities not exempt from reporting must file annual reports with the EPA due March 31st for the previous calendar year.

Currently, the NRC, EPA and Agreement States may inspect and enforce this rule. Records related to compliance with the NESHAP standards must be maintained for a period of five years. In December 1994, the EPA published a notice, entitled *Federal Radiation Protection Guidance of Exposure to the General Public* (*20*), that in part appears to be in conflict with the current NESHAP criteria of a general public dose limit of 0.1 mSv. In this notice the EPA, as the radiation advisor to the President and federal agencies including the NRC, made seven recommendations, or Radiation Protection Guides. Recommendation 3 (*20*), which proposes a new RPG for the general public, states:

> The combined radiation doses incurred in any single year from all sources of exposure covered by these regulations, should not normally exceed a Radiation Protection Guide of 1 mSv (100 mrem) effective dose equivalent to an individual.

It appeared that the NRC and EPA might finally agree on what an ample margin of safety is for public radiation exposure.

In another apparent conflict, the EPA published a notice in the *Federal Register* (*21*) in September, 1995, requesting comments pertaining to the recision of Subpart I (Radionuclide NESHAPs) for NRC and Agreement State licensees. The stringent emission standards will remain, only the regulating agency will change.

Although the EPA has the statutory authority to rescind the NESHAP for radionuclides, it is unlikely that the EPA administrator will do this unless the NRC adopts the NESHAP into 10 CFR 20, Appendix B. Only this will assure the EPA of an ample margin of safety with respect to radionuclide emissions.

It appears the these standards will be present for some time and will be incorporated into the annual activities of radioactive materials licensees. Fortunately, the majority of licensees will not have to alter possession and use criteria to remain in compliance and, through the use of the COMPLY program, calculations related to demonstrating compliance are significantly simplified. Our observations lead us to believe that the EPA estimate of 99% compliance with the radionuclide NESHAP standards is accurate.

REFERENCES

1. Code of Federal Regulations, Title 10, Part 20 Appendix B. Office of the Federal Register, National Archives and Records Service. Washington, DC: General Services Administration; 1994.
2. *Federal Register*, Vol. 59, No. 246; Washington, DC: General Services Administration; 1994:66414.
3. *Federal Register*, Vol. 54, No. 43; Washington, DC: General Services Administration; 1989:9614.
4. *National Resources Defense Council, Inc. v. EPA*, 824 F.2d at 1146 (1987).
5. *Federal Register*, Vol. 54, No. 43; Washington, DC: General Services Administration; 1989:9612–9614.
6. *Federal Register*, Vol. 54, No. 240; Washington, DC: General Services Administration; 1989:51698.
7. *Federal Register*, Vol. 59, No. 19; Washington, DC: General Services Administration; 1994:4228.
8. *National Resources Defense Council, Inc. v. Reilly*, 976 F.2d 36 D.C. Cir. (1992).
9. *Federal Register*, Vol. 59, No. 19; Washington, DC: General Services Administration; 1994:4228.
10. *BEIR V: health effects of exposure to low levels of ionizing radiation*. Washington, DC: National Academy Press; 1990.
11. *Federal Register*, Vol. 54, No. 43; Washington, DC: General Services Administration; 1989:9615.
12. *National Resources Defense Council, Inc. v. EPA*, 824 F.2d at 1165 (1987).
13. Code of Federal Regulations, Title 40, Part 61.102. Office of the Federal Register, National Archives and Records Service. Washington, DC: General Services Administration; 1989.
14. *Federal Register*, Vol. 54, No. 43; Washington, DC: General Services Administration; 1989:9630.
15. Code of Federal Regulations, Title 40, Part 61.104(b). Office of the Federal Register, National Archives and Records Service. Washington, DC: General Services Administration; 1989.
16. SNM Newsline. Environmental Protection Agency Clean Air Act. *J Nucl Med* 1993;34:34N.
17. *A guide for determining compliance with the Clean Air Act standards for radionuclide emissions from NRC-licensed and non-DOE federal facilities, revision 2*. Washington, DC: Environmental Protection Agency; 1989:3–42.
18. *Student training manual: conducting radionuclide NESHAPs inspections at NRC and Agreement State Licensee 40 CFR 61 Subpart I*. Washington, DC: Environmental Protection Agency; 1994:2–5.
19. *User's guide to the COMPLY Code, Revision 2*. Washington, DC: Environmental Protection Agency; 1989:3–19.
20. *Federal Register*, Vol. 59, No. 246; Washington, DC: General Services Administration; 1994:66414, 66420.
21. *Federal Register*, Vol. 60, No. 188; Washington, DC: General Services Administration; 1995:50162.