



Clean Agent Extinguishing Systems  
Revised rules for safe human exposure

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The sales video showed a man sitting alone in a glass-walled phone booth looking relaxed and smiling into the camera. Suddenly, a cloud of halon 1301 fire extinguishing agent filled the booth. To my surprise, the man continued sitting and smiling at the audience for several minutes, unharmed, and breathing normally.

It was surprising that the man was unharmed by the gaseous extinguishing agent because, at the time, carbon dioxide was the most commonly used gaseous extinguishing agent. It was well known that the man would have been asphyxiated if the booth had been flooded with carbon dioxide.

The video dramatically illustrated that this new gaseous agent, halon 1301, was different. It seemed safe for humans to breathe. Halon 1301 ushered in a new paradigm of clean, dry fire suppression in normally occupied spaces that was not harmful to humans.

Halon 1301, indeed, had several characteristics that make it ideal for use as a total flooding fire extinguishing agent in normally occupied spaces. The chemical was delivered into the protected space as a gas that permeated the entire space, even inside equipment cabinets, leaving no damaging residue. Halon 1301 seemed like the perfect answer to fire protection needs in mission-critical areas such as computer rooms and telecommunication centers. The agent/air mixture could effectively extinguish fires at concentrations that weren't harmful to humans, and was also electrically nonconductive. Possessing all of these important attributes in a single extinguishing agent, halon 1301 was revolutionary.

Halon 1301 was introduced to the marketplace and established an initial foothold in the late 1960s and early 1970s. NFPA 12A, Halon 1301 Fire Extinguishing Systems, was first published in 1971. During the subsequent two decades, halon 1301 gained enormous popularity and was used in a wide variety of applications where its attributes were of particular value.

The rules in the early editions of NFPA 12A regarding safe human exposure were very simple and are summarized in Table 1. Halon 1301 was commonly used in concentrations between 5 percent and 6 percent. Accordingly, it could be used in normally occupied spaces with no formal restrictions relating to duration of human exposure.

Halon 1301 Design Concentration	Restrictions Related To Human Exposure
7 percent	None
> 7 percent and 10 percent	Egress possible in 60 seconds
> 10 percent and 15 percent	Space not normally occupied Egress possible in 30 seconds

On September 16, 1987, the United States and 23 other nations signed the Montreal Protocol, which was adopted into US law through the Clean Air Act of 1990. These new laws scheduled the phase out of production of ozone depleting substances (ODS) that were causing destruction of stratospheric ozone. Stratospheric ozone is an essential minor atmospheric constituent responsible for the absorption of harmful UV-B radiation. The ODS chemicals are primarily chlorine and bromine containing gases, each of which has a characteristic potency for destroying ozone called the Ozone Depletion Potential (ODP). Halon 1301, as it turns out, has the highest ODP of any man-made ODS. Since the cessation of production of halon 1301 in 1994, new fire extinguishing agents have been developed to serve as alternative fire extinguishing agents.

Many of these new gaseous agents have attributes similar to those of halon 1301 including low toxicity to humans, nil electrical conductivity, and are "clean," i.e., they leave no damaging residue. These new "clean agents" are addressed by NFPA 2001, Clean Agent Fire Extinguishing Systems<sup>2</sup>, first published in 1994. Subsequent editions were issued in 1996, 2000, and most recently in February 2004.

Today, the rules for human exposure to clean agents are much different than they were originally for halon 1301. These rules have been expanded to address 13 different clean agents – each with unique toxicity characteristics. Revisions have been made to incorporate exposure rules developed from scientifically based analysis methods. The new rules must be understood and applied correctly to maximize fire protection system flexibility and cost effectiveness while preserving a high level of protection for human safety. Many clean agents can be used safely in normally occupied spaces when applied correctly.

Clean agent toxicity

NFPA 2001 addresses two types of gaseous clean agents: inert agents and halocarbon agents. The health risks associated with these two agent types are quite different. The human health risk for the use of inert agents is hypoxia.

Hypoxia is an insufficient level of oxygen reaching the tissues and organs in the body. Hypoxia can result from breathing air that has a low oxygen concentration.

Inert clean agents extinguish fires by displacing oxygen to levels at which combustion cannot be sustained. This creates a hypoxic atmosphere that is potentially harmful to humans. The degree of potential harm is related to the oxygen concentration and the length of time that the human breathes the hypoxic atmosphere. At extremely low oxygen concentrations (below 8 percent), exposure is potentially fatal.

The principal health risk for humans exposed to halocarbon agents is cardiac sensitization. Cardiac sensitization is defined as the presence of extra or premature ventricular contractions due to exposure of the mammalian heart to high concentrations of certain organic chemicals. This sensitivity is increased in the presence of adrenaline. Cardiac sensitization can result in cardiac arrhythmia, and possibly death.

It has been known since the early 1900s that inhalation of certain anesthetic agents, such as chloroform, can sensitize the heart to adrenaline. Today, it's known that other halocarbon compounds can also create cardiac sensitization.

If air containing halocarbon clean agent gas is inhaled, some of the halocarbon gas will be absorbed into the bloodstream through the lungs. The concentration of the dissolved halocarbon gas in the bloodstream is related to the gas concentration in the inhaled air and to the length of time of exposure. If the exposure is long enough, an equilibrium concentration of dissolved halocarbon gas in the blood of the exposed person will be reached. If the blood concentration is high enough, the heart can become sensitized to adrenaline. In the presence of a high level of adrenaline, a heart can experience a cardiac arrhythmia.

NFPA 2001 employs two threshold value concepts to help define requirements for safe human exposure. The no observed adverse effect level (NOAEL) is the highest concentration at which no adverse toxicological or physiological effect was observed. The lowest observed adverse effect level (LOAEL) is the lowest concentration at which an adverse physiological or toxicological effect was observed.

For inert clean agents, the NOAEL and LOAEL values are expressed in terms of agent design concentration and relate directly to a corresponding oxygen concentration.

For halocarbon agents, the NOAEL and LOAEL values are expressed in terms of agent design concentration and relate to agent concentrations derived from cardiac sensitivity testing performed using beagles following a standard test protocol originally developed by DuPont3.

The NOAEL and LOAEL values for all clean agents currently listed in the 2004 edition of NFPA 2001 are shown in Table 2.

**TABLE 2**

CLEAN AGENT	NOAEL (AGENT percent BY VOLUME)	LOAEL (AGENT percent BY VOLUME)
FC-3-1-10	40.0	>40.0
FK-5-1-12	10.0	>10.0
HCFC Blend A	10.0	>10.0
HCFC-124	1.0	2.5
HFC-125	7.5	10.0
HFC-227ea	9.0	>10.5
HFC-23	30.0	>50.0
HFC-236fa	10.0	15.0
FIG-130i	0.2	0.4
IG-01	43.0	52.0
IG-100	43.0	52.0
IG-541	43.0	52.0
IG-55	43.0	52.0

**Safe Human Exposure Rules Development**

For both the inert and halocarbon clean agents, the basic NOAEL and LOAEL values are related directly to exposure duration for normally occupied and not normally occupied spaces. The specific relationship between the NOAEL and LOAEL values and exposure duration was determined for both types of clean agents with assistance from expert panels assembled by the U.S. Environmental Protection Agency (EPA)

Human exposure limitations to inert clean agents published in early editions of NFPA 2001, which were very simple and quite restrictive, are summarized in Table 3.

Subsequently, a panel of experts on hypoxia was convened by EPA to study the physiological effects of hypoxic atmospheres created by the various inert clean agents covered in NFPA 2001. This panel met in 1995 and again in 1997. The work of this panel was formulated into a set of consensus opinions that were reviewed by the NFPA technical committee. As a result, the human exposure limitations in the standard were revised. The current limitations are summarized in Table 4.

**TABLE 3**

AGENT DESIGN %	OCCUPANCY	EXPOSURE TIME LIMIT	COMMENTS
43	Normally Occupied	No limit	
> 43	Not Occupied	No exposure allowed	
43 > 43 and 53	Occupied	No exposure allowed	Exception created for Class B fuel hazards

The human exposure limitations for halocarbon clean agents published in the early editions of NFPA 2001 were the same as those for inert clean agents. They were very simple and quite restrictive. These limitations are summarized in Table 5.

A look at how these limitations would be applied to halon 1301 illustrates just how restrictive these rules were. Halon 1301 has a NOAEL value of 5 percent and a LOAEL value of 7.5 percent. It was most commonly used at design concentrations of between 5 percent and 6 percent in normally occupied spaces with no restrictions on exposure time (see Table 1). Under the limitations for clean agents (see Table 5), halon 1301 systems designed above 5 percent would have been allowed in only spaces not normally occupied.

AGENT DESIGN %	OXYGEN %	OCCUPANCY	EXPOSURE TIME LIMIT
43	12	Normally Occupied	Up to 5 minutes
> 43 and 52	< 12 and 10	Normally Occupied	Up to 3 minutes
> 52 and 62	< 10 and 8	Not Occupied	Up to 30 seconds
> 62	< 8	Not Occupied	No exposure allowed

Many halon 1301 systems have been installed to provide agent concentrations above 5 percent in protection of normally occupied spaces under the human exposure rules in NFPA 12A. There's more than 30 years of experience using these systems indicating that they are safe in terms of human exposure. This fact underscored the need to understand more about the science of safe human exposure to halocarbon clean agents.

AGENT DESIGN %	OCCUPANCY	EXPOSURE TIME LIMIT	COMMENTS
NOAEL	Normally Occupied	No limit	
> NOAEL	Not Occupied	No exposure allowed	
LOAEL	Occupied	No exposure allowed	Exception created for Class B fuel hazards

EPA convened a panel of cardiotoxicity experts to evaluate the science underlying safe human exposure to halocarbon agents in 1995. This panel recommended further research to adapt Physiologically Based Pharmacokinetic (PBPK) modeling techniques to the process of establishing safe exposure limits for halocarbon clean agents. PBPK analyzes the interactions between drugs and the human body relative to absorption, distribution, metabolism, and excretion. PBPK modeling was a well-established scientific field of study as of 1995. Subsequent to the expert panel's recommendations, several studies were conducted relative to adapting the PBPK modeling process to the problem of establishing safe human exposure levels for halocarbon clean agents.4, 5, 6, 7, and 8

The PBPK studies resulted in a revised and calibrated PBPK modeling process to quantitatively evaluate short duration human exposures to halocarbon clean agents. An input to the human model for a given clean agent is related to the arterial blood level of the agent during the occurrence of 3 to 5 extra beats of the canine heart (defined as the agent's LOAEL). The agent's LOAEL value is determined by a standardized cardiac sensitivity test using beagles.

In this test, beagles (normally six dogs) are administered an injection of epinephrine that will result in an increased sensitivity of the heart to extra beats (epinephrine is synthetic adrenaline). The amount of epinephrine injected is just below that which will cause a cardiac arrhythmia (heart attack) all by itself. This amount is approximately 10 times that which the dog can produce on its own. The dog's heart response is continuously recorded by electrocardiogram (ECG).

The test dogs are then subjected to a specified concentration of the clean agent being tested. After a period of 5 minutes of breathing the agent/air mixture, they receive a second challenge injection of epinephrine. This determines if the agent concentration inhaled by the dog sensitized the heart. If so, the ECG would show an arrhythmia coinciding with the challenge injection. If an arrhythmia is detected, a sample of the dog's blood would be taken and the arterial blood concentration of the clean agent would be measured. If no arrhythmia was detected, the test would be repeated at a higher concentration of agent until an arrhythmia is produced. The lowest agent concentration that produces an arrhythmia is the LOAEL value for that clean agent. The highest tested concentration that produced no arrhythmia is the NOAEL value.

The dog's arterial blood concentration measured at the clean agent's LOAEL concentration after a 5-minute exposure is used as an input to the PBPK model. This value is the target value for humans in the PBPK model. The PBPK model is used to predict how long it will take for this target value to be reached in the arterial blood of a human being exposed to a given concentration of clean agent. The time value is safe for human exposure to the clean agent at that concentration.

NFPA 2001 has revised its rules for safe human exposure several times to incorporate the use of the PBPK model as it was being developed. The current rules in the 2004 edition are shown in Table 6.

The following example is presented to help illustrate the rules in Table 6 related to the use of PBPK data.

Halocarbon clean agent X is proposed for use in a normally occupied space at a design concentration of 10 percent. The NOAEL value for this agent is 8 percent and the LOAEL value is 9.5 percent. Under the original human exposure rules, this proposed design could only be used for a space not normally occupied because the design concentration exceeds the LOAEL value. Furthermore, design would have to ensure that occupants of the room would evacuate before agent discharge.

Now, let's apply the PBPK model to this example. The PBPK model needs, as input, the arterial blood level measured in the beagle dog that experienced a heart arrhythmia at the LOAEL concentration of 9.5 percent. This value is loaded into the PBPK model, as is the desired design concentration of 10 percent. The PBPK model calculates the human exposure time that will allow the human arterial blood concentration of agent to reach the same level as the input value from the dog. The result is 6 minutes.

In this example, the PBPK model determines that a human being can safely be exposed to an agent concentration of 10 percent for up to 6 minutes. The second row of Table 6 applies to this case. This result indicates that the proposed design is safe for use in normally occupied spaces and no special approvals are needed or special conditions apply. The system design must limit human exposure to 5 minutes, even though the PBPK model predicts that 6 minutes is safe.

Let's alter this example slightly to illustrate other provisions within the safe exposure rules. Assume that the PBPK model determines that a human being can safely be exposed to an agent concentration of 10 percent for only 3 minutes. For this case, the third row of Table 6 applies. Special conditions must be satisfied to allow this proposed design to be used in a normally occupied space. Egress calculations must be performed to demonstrate that all occupants of the space can egress within 3 minutes corresponding to the PBPK model result. Furthermore, special approval from the authority having jurisdiction (AHJ) must be obtained.

#### Additional clarifications

Several additional clarifications may be helpful. The rules intend to prevent human exposure to all clean agents. NFPA 2001 generally requires clean agent systems to be provided with pre-discharge alarms and time delays to help facilitate occupant egress from the protected space before discharge.

The rules summarized in Table 6 address halocarbon clean agents that have PBPK data available and those that do not. The standard intends that a person accidentally exposed to any clean agent after discharge will be exposed for no more than 5 minutes. It is the intent of the NFPA 2001 standard that clean agent systems be used only in occupancies where occupants can egress within 5 minutes. This applies to both inert and halocarbon clean agent systems. The new revised rules for safe human exposure to gaseous clean agents in the 2004 edition of NFPA 2001 are based on advice from panels of scientific and medical experts and on extensive research. These rules must be understood and applied carefully to the design of each clean agent fire extinguishing system.

#### Endnotes

1. NFPA 12A, Halon 1301 Fire Extinguishing Systems, NFPA, One Batterymarch Park, Quincy, MA.
2. NFPA 2001, Clean Agent Fire Extinguishing Systems, NFPA, One Batterymarch Park, Quincy, MA.
3. "Cardiac Sensitization: Methods Development and Understanding The Hazard and Potential Risk", W.J. Brock, DuPont Fluoroproducts, Halon Options Technical Working Conference May 12-14, 1998.
4. "Cardiac Sensitization Thresholds of Halon Replacement Chemicals Predicted in Humans by Physiologically-Based Pharmacokinetic Modeling", A. Vinegar and G.W. Jepson, Risk Analysis, Volume 16, Number 4: 1996.
5. "PBPK Modeling of Short Term (0 to 5 min) Human Inhalation Exposures to Halogenated Hydrocarbons", A. Vinegar, G.W. Jepson, and J. H. Overton, Inhal. Toxicol 10:411-429: 1998.
6. "Performance of Monte Carlo Simulations of Exposure to HFC-227ea", A. Vinegar, ManTech Environmental Technology, Inc., Dayton, OH: February 1999.
7. "Setting Safe Exposure Limits for Halon Replacement Chemicals Using Physiologically Based Pharmacokinetic Modeling", Inhal. Toxicol, A. Vinegar, GW Jepson, M. Cisneros, R. Rubenstein, and W. J. Brock.
8. "Physiologically Based Pharmacokinetic Model to Establish Safe Exposure Criteria for Halocarbon Fire Extinguishing Agents", FP 44/INF.2, submitted by the US International Maritime Organization, 4 Albert Embankment, London SE1 7SR, England: November 1999.

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AGENT DESIGN %	OCCUPANCY	EXPOSURE TIME LIMIT	COMMENTS
NOAEL	Normally Occupied	Up to 5 minutes	No PBPK data needed
> NOAEL and LOAEL	Normally Occupied	PBPK model limit corresponding to design concentration and 5 minute exposure	PBPK data needed
> NOAEL and LOAEL	Normally Occupied	PBPK model limit corresponding to design concentration and less than 5 minute exposure	Conditions: 1. AHJ approval 2. Egress time calculations 3. Adhere to PBPK model exposure time limitation
> LOAEL	Not Occupied	PBPK model limit corresponding to the design concentration	PBPK data needed
LOAEL	Not Occupied	Up to 60 seconds	No PBPK data available
> LOAEL	Not Occupied	Up to 30 seconds	No PBPK data available