RD/GD-352 Design, Testing and Performance of Exposure Devices

Comments received during public consultation

First consultation: December 21, 2010 – February 7, 2011

Feedback on comments: February 18 – March 4, 2011

	Section #	Reviewer Name/ Organization	Comment	CNSC Response
1	2.3.3	Brian Sargent Industrial Radiography Supplies and Services Inc.	Safety devices – Operation of the automatic securing mechanism A definition should be given for “a shutter” and/or a “shutter device”	The following definition for the shutter was added to the guide: Shutter is a system or device inside the source container between the shielded and unshielded position of the source that may be operated manually, electrically or pneumatically by a source control mechanism. Section 2.3.3 of the guide applies to a shutter that is used for shielding of the source when in secured position.
2	2.3.4	Brian Sargent Industrial Radiography Supplies and Services Inc.	Remote control security An acceptable amount of leakage should be established (if any) by the manufacturer with consideration of environmental or other hazards.	Agreed. Section on remote control security was removed.
3		Chris Spencer Spencer Manufacturing (1983) Ltd.	This document references ISO3999:2004 but the CNSC does not provide the ISO document as part of the draft material. Access to this documentation requires the payment of a fee to ISO and that may limit the number of people who will choose to comment on this draft document.	CNSC recognizes that this may limit the extent of comments received on the draft document, however the ISO standard is protected by copyright and as such CNSC could not provide the document as part of the draft material. The CNSC expects that those stakeholders, such as manufacturers and designers who will be using this RD/GD-352 document would already have access to the standard or would be willing to pay the fee to access to the standard.

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4	2.3.5.2	Chris Spencer Spencer Manufacturing (1983) Ltd.	“Endurance test “seems to have little use as even the least robust designs will easily withstand the quantity of cycles required in ISO 3999:2004. • The problem is that the quantity of cycles required by ISO 3999:2004 are too low, they do not represent even a fraction of the useful life of an average exposure device being used in western Canada. • An average radiographer can easily manage 120 welds (360 exposure cycles) per day on a pipeline. • At that level of work 50,000 cycles can be exceeded in just 139 days. • Some companies run two or even three shifts of evaluating fabrication work which mean the exposure devices may be operating 20 to 24 hours a day and six or seven days per week. • I would suggest a worst case scenario of 30 Welds per hour (90 exposures) for fabrication and 15 Welds per hour (45 exposures) for Pipeline. • If one were to use the worst case scenario of 24 hours a day 350 days a year at 90 cycles per hour that would result in an exposure device being cycled 756,000 times per year. • Although it is extremely unlikely a device would see 750,000+ cycles per year in real life, ALARA dictates we use worst case scenarios because the devices do not currently employ a method of counting the number of cycles. • I believe the only way to solve the problem is to stop guessing at the number of cycles and require that all certified exposure devices shall incorporate a robust mechanism to count the number of cycles each exposure device is subjected to and add tests that simulate real life conditions. • Examples of possible changes to endurance testing: A) The device manufacturer shall specify the useful life of a device in quantity of cycles • At the end of the useful life the device shall be returned to the manufacturer for evaluation and refurbishment to OEM specifications. B) The device manufacturer shall specify a maintenance program directly related to the number of cycles and time. • The manufacturer shall specify the type of maintenance and or inspection at each cycle interval including methodology/schedule to evaluate the integrity of the cladding or encasement of the shielding. C) The device manufacturer perform endurance tests in accordance with ISO3999:2004 section 6.2.3, but substitute the quantity of 50,000 cycles with the statement: • “Number of cycles shall be equivalent to 1.5 times the maximum cycles	The comments bring good suggestions for improving the ISO 3999 standard. While the CNSC considers the endurance test requirements in the current edition of ISO 3999 to be adequate, if the equipment is used, inspected and maintained in the field in accordance with the manufacturer’s instructions, the CNSC will be submitting these comments for improvement to the ISO 3999 writing group for consideration during its next revision cycle.

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			specified in section B(i) of the preventative maintenance program" • ** if for example the device manufacturer specifies 60,000 cycles in between maintenance requirements the device shall be cycled 90,000 cycles without failure of the system, the tests shall be conducted without interruption in accordance with section 6.2.2 of the ISO 3999:2004 standard. D) The device manufacturer shall cycle the device to the quantity of cycles specified in section A(i) with interruptions in accordance with the regular maintenance intervals specified in section B(i) • Any failure of the system shall be investigated for root cause prior to continuation with testing and inserted as an addendum to the application for certification. • Components that have caused failure within the exposure device or accessories shall be replaced at interval that shall not exceed 0.75 times the number of cycles it took to fail • This simple approach to endurance testing ensures that devices will ideally operate flawlessly between maintenance periods; it will ensure that the source channel integrity is monitored and it will ensure that components known to fail at a particular quantity of cycles will be replaced prior to failure. • With this approach it puts the pressure on the manufacturer to create a robust design and ensure their device can withstand several hundred thousand if not several million cycles without failure. • If device manufacturer A puts a lifetime of 7 years or 750,000 cycles and manufacturer B puts a lifetime of 20 years or 2,000,000 cycles then customers purchasing exposure devices will of course pick the more robust design so long as the economics are scaled in favour of the second device.	
5	2.3.7	Chris Spencer Spencer Manufacturing (1983) Ltd.	"Labelling" could use some additions to help inspectors identify and enforce maintenance on individual components of the system • CNSC Inspectors are commonly writing up companies on maintenance and randomly asking that they serialize their components. • As an example, some inspectors have told my clients they must identify their PAR 100-3 guide tube source stop in a manor which allows them to prove that they have been maintained. • This is however not enforced on GammaMat, QSA, INC, SPEC guide tubes despite their similar requirements for maintenance, so it has been considered by many to be an unfair and inconsistent requirement • Given there is no specific requirement to serialize individual components of the	Section 7 of the ISO standard still applies: "Marking," which includes marking of the serial number on the exposure container, source holder or source assembly and the sealed source. Critical components are required to have labels to identify the manufacturer. Additional labelling requirements are spelled out to ensure that the labelling meets the requirements of the CNSC regulations. Suggested labelling requirements are beyond the scope of this document and may be used by the user to identify the serial numbers of the accessories. Routine inspections and proper maintenance should ensure that defective accessories are not used in the field.

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			exposure device and accessories, most manufacturers have not provided suitable methods of identifying those components. • If your OIS group is set on serializing accessories such as guide tubes, source stops, controls, then I would suggest that you add it to this section on labelling to facilitate the requirement across all devices.	Good point on consistency during inspections which should be set out in CNSC procedures. CNSC worksheets will be reviewed to ensure consistency and determine if there is a need for “serialization” of the components.
6	2.4.1	Chris Spencer Spencer Manufacturing (1983) Ltd.	Confusing with respect to the “locking mechanism” and “inadvertent release of the source while transferring” • Is this referring to a requirement for an “automatic lock” or the typical key lock/plunger design with “teeth” that push into the source assembly to secure it? • The act of “transferring” indicates that the source is in motion and has already been released from it’s locked position • I’m wondering if this was a statement to ensure that the source does not move out of the fully shielded position inadvertently while connecting or disconnecting the drive cable from the source assembly.	The text was revised to the following: ‘Source changers should be designed to ensure that the source will not be accidentally withdrawn from the source changers when connecting or disconnecting the drive cable to or from the source assembly. Source changers should also be equipped with a locking mechanism designed to prevent the unauthorized or accidental removal of the sealed source from its shielded position.’
7	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 5.3 sets out a table of ambient equivalent dose rate limits which are relatively high considered the quantity of time the CEDO’s are in close proximity to the devices. • When one works out contact dose rates to skin and levels of radiation to the organs (less than 0.5m) the quantity of time required to exceed regulatory limits is significantly less than a year, in some cases the worst cases scenario is 250 hours per year (contact with skin) • The largest problem with the ISO 3999:2004 standard is that it does not specify maximum dose rates to CEDOs during the use of the exposure device. • Maximum source capacity is only related to the device in the fully shielded position, the standard does not take into account the levels of radiation while the source outside of a Category II device • A very significant portion of the dose received by the CEDO is related to the “flash dose” while the source assembly is passing through the unshielded exposure sheath. • If limits were set for the maximum ambient equivalent dose rate while the source was in the unshielded position it would force the manufacturers to come up with unique ways to reduce operator dose. • Perhaps they would start to implement shielding around the exposure sheath, limit the minimum length of control that could be used, increase the source travel speed, invent portable shielding devices, create automated control systems that can be actuated from long distances, create designs that are still Category II but can be converted to Category I with the addition of an accessory, create	The requirements set-out in section 5.3 of the ISO standard are the maximum allowable dose rates from the device while in a shielded position. The suggestions provided apply to the use of the device rather than its design and are thus beyond the scope of this document. The safety requirements for the operation are evaluated at the time of licensing and compliance and are verified accordingly. The recommendation could be used as an industry good practice.

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			exposure devices which can operate in both Category I and Category II modes. • In short the lack of innovation in this industry is due to the lack of limits on equivalent dose rates. • Manufacturers meet the requirements in the standards and stop there; they have little reason to sink money into development of accessories that exceed standards or regulatory requirements.	
8	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 5.4.2 specifies the use of a radiation survey meter that should be in accordance with IEC 60846 • This standard has been withdrawn by IEC and replaced with a newer standard IEC 60846-2. • Perhaps an upgrade to a newer version or an equivalent Canadian standard could be used	In January 2011, the CNSC reviewed several older documents as part of an ongoing process to ensure that all documents contained current and relevant information. Two documents, R-116 *Requirements for Leak Testing Selected Sealed Radiation Sources* and R-117 *Requirements for Gamma Radiation Survey Meter Calibration* were determined to be outdated as they referred to the former Atomic Energy Control Board. In addition, it should be noted that the CNSC no longer certifies persons or companies for carrying out leak testing services or gamma radiation survey meter calibrations. Therefore, these documents were removed from the CNSC Web site. IEC 60846 was split into two parts. Part I (IEC 60846-1) which was published in 2009 deals with portable workplace and environmental meters and monitors and Part II (IEC 60846-2) which was published in 2007 deals with emergency situations and high energy dose rates. For this document, Part I applies. The document was revised to provide greater clarification.
9	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 5.4.2 required indications of secured position and references the use of a radiation survey meter • Why is it still common practice to approach an exposure device and measure surface readings when ALARA would dictate that the best methodology is to assess the surface readings from a distance? • It is a simple task to integrate a detector into a portion of the device and wirelessly transmit the effective dose rate data back to the user. • Users commonly enter a radiation field that can exceed 0.2mSv/h in order to verify the position of the source, ALARA would dictate that it would be safer to measure the surface 10m away from the device while they standing at the end of their control mechanism. • Additionally if there is an exposure device malfunction the remote measurement of the field strength would ensure that users do not subject themselves to high dose rates as they approach the device	Adding complex electronic components would add complexity to the design and would require more maintenance, particularly when used in Canada's extreme weather conditions. Although beyond the scope of this guide, it is expected that the manufacturer's operating instructions will provide guidance for minimizing an operator's exposure.

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10	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 6.4.1.2 specifies the ISO 7503-1 standard from 1988. • is this still applicable or can it be substituted with a Canadian equivalent such as R-116?	The latest edition of ISO 7503 Part 1 is the 1988 edition. R-116 is obsolete – the CNSC is looking at alternative options with respect to regulatory guidance for leak testing.
11	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 5.4.1.2 specifies that the devices use an Automatic securing mechanism • Although on the surface this seems like a good idea, the fact is that these mechanisms increase the quantity of parts interacting within the exposure device. • Given the extreme conditions of the Canadian environment I believe there is a direct trend linking the complexity of the design to the number of malfunctions/ incidents. • I am of the opinion it was the addition of the mechanical source position indicators that reduced the number of incidents and that the automatic securing mechanisms have actually increased the number of incidents. • If a very simple device not compliant with 5.4.1.2 were upgraded with wireless dose rate monitoring and either mechanical or electrical based source position indicators I believe it would increase reliability and decrease the number of incidents related to the malfunction of the rather complex locking mechanism. • Additionally the requirement for an automatic securing mechanism has limited the design of the source holders which may reduce operational speed, thus violating ALARA • ALARA dictates that time is a significant factor, given a set length of guide tube the only variable affecting the time is the speed at which the source travels from the fully shielded position to the exposure head. • Increase the speed and there will be a proportional decrease in dose to the operator and public. • If the use of the automatic securing mechanism and thus complex source holder design decreases the speed of source travel then it is not in accordance with ALARA • Let's say we have 1000 exposure devices working in Canada and their average dose from operating these devices is 10mSv per year. • That represents an industry dose of 10Sv per year. • By increasing the speed of the source travel by 50% the net result would be a reduction in dose of at least 30% which represents a dose reduction of 3 Sv per year. • It stands to reason that there will always be incidents due to human factors, increasing the complexity of the devices may not change this fact.	RD/GD-352 does not prevent the designer from incorporating these suggestions, and industry to adopt them as good practices. However it was determined that inclusion of these in the document would add a level of prescription that is not necessary to ensure an acceptable level of safety.

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			• Even if there was a small increase in incidents due to the removal of automatic locking mechanisms, from an over all perspective the 3 Sv per year reduction should outweigh that of the increased number of incidents. • If the detection equipment was “fail safe” and integrated into the device it would be quite simple to ensure that a device can not be unlocked unless all of the source position safety features are fully functional. • In short, the narrow focus of ISO 3999 and other standards have created a situation where the industrial radiography industry can not further reduce their dose	
12	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 5.8.3 specifies that at the conclusion of testing the force required to operate and exposure device shall not increase by more than 125% • This standard does not give a base line for maximum force, it is possible that a design may require sufficient force to begin with and that an increase to 125% may exceed the limits of the force that can be applied without deformation of the control system. • It is common for current designs to exhibit elastic deformation in the control system, the inside diameter of the control sheath is typically large enough that the flexible Teleflex can create a temporary pattern of deformation (sinusoidal) , thus increasing the friction and decreasing the force available to move the sealed source assembly • Current designs rely upon Teleflex, but it is an expensive product that can be damaged very easily by water (rusting if not lubricated) • Manufacturers get around this by adding lubricants, which combine with dust/dirt to deposit foreign materials into the locking mechanism and the source channel. • Testing in a controlled environment can not simulate field conditions; the environment is too unpredictable to be simulated. • One solution is to include a mechanism to measure the forces require during operation, it would be simple enough to integrate a pressure transducer within the crank mechanism. • This way if an operator makes the bend in the controls or guide tube and the force exceeds specifications the system can log the error and corrective action can be taken by the licensee. • This would also help indicate if service is required. • Increase in force almost always results in reduction of source travel speed, therefore it is important to ensure that performance of the system be monitored. • Realistically the best way to do this is to get rid of manual controls all together and have all of the system parameters controlled and monitored by a	The projection test requires measurement of the force required to operate the system prior to performing all other tests. At the conclusion of normal condition testing, the force required to operate the control assembly should be within 125% of original measurement and the equipment must remain completely operational. The equipment must therefore withstand any increase in the forces. As suggested in the response to comment #11, some suggestions made may relate to good exposure device design and safety practices that may improve exposure doses to workers. RD/GD-352 does not prevent the designer from incorporating these suggestions. Some of the comments made are beyond the scope of this guide as they relate to the use of the device rather than its design and testing. The suggestions could be adopted by industry as good practice.

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			microprocessor. • Today's military spec components could easily withstand Canadian environmental conditions, if the entire apparatus is controlled via remote wireless technology using a secure digital algorithm the human factors would be removed from the equation.	
13	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 5.8.4 specifies tests for the exposure container which simulate possible scenarios that might be encountered while the container is being moved from point A to point B but they do not take into account the fact that the majority of movement consists of the exposure device and all of its accessories. • Typically exposure device operators do not remove guide tubes and controls from the exposure container while moving from weld to weld, the only time the device is not connected to accessories is just before or after transport. • One case where this might be an exception is the instance where a radiographer is carrying an exposure device up a ladder to a piece of work situated high in the air, but the current tests do not simulate this condition, the only applicable test would be from the 9m drop test out of the IAEA requirements. • As such the 1.2m drop test is useless, unless all of the accessories are attached at the time of the test. • Perhaps all exposure devices should be dropped with two criteria: • Exposure device dropped from 9m without accessories attached • Exposure device dropped onto a metal bar from 2m with accessories connected	In accordance with section 5.1.1 of the ISO standard, "Apparatus for industrial gamma radiography shall be designed for the conditions likely to be encountered in use." When the manufacturer's instructions for operation and maintenance procedures for the exposure device and its accessories are followed by the user, the testing requirements provided in the ISO standard are adequate. The device must not be moved from point A to point B with its accessories connected to the camera. The CNSC *Packaging and Transport of Nuclear Substances Regulations* must be followed for the transportation of the device. These regulations provide requirements for design and testing of transport containers. With regards to the performance requirements as an exposure device, the comments bring good suggestions for improving the ISO 3999 standard and the CNSC will evaluate these suggestions for possible submission of these comments for improvement to the ISO 3999 writing group for consideration during its next revision cycle.
14	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 6.6 and 6.7 describes the principal for accessory testing as a simulation of being crushed by the heel of a person's footwear • This is a ridiculous test, at no times should there be a situation where people are walking on the accessories, the more likely scenario for incidents are: 1) Exposure device falls from a position when the accessories are secured by fastener 2) An object from the work site falls onto the accessories (most commonly a loose pipe) • In general the crush tests are far too easy to pass, one can permanently crush and disable a current accessory from any cable based exposure device with simple hand pressure (as demonstrated at a CNSC working group meeting) • The guide tube of a Pneumat-a-ray 100-3 projection sheath can be driven over by a truck or crushed with a 4" diameter pipe without permanent damage because it does not contain metallic compounds.	The test simulates crushing of the remote control sheath with its contained control cable by the heel of a person of mass 150 kg impacting at a horizontal and vertical speed of 0.8 m/s. The concerns raised and the suggestions provided are valid and will be brought forward in the next revision cycle of ISO standard.

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			• These two sections fail to address real life working conditions, they are pointless as written. • A perfect example is a situation where an exposure head is held securely on the pipe and the exposure device is situated on top of a pipe 1.5m in height. • The operator may accidentally pull the exposure device to the side when straightening the remote controls just prior to operation; the result is a situation where the weight of the exposure device kinks the exposure sheath making it completely unusable. • Worse yet, this could happen while the source is exposing the film at the end of the sheath making it impossible to return the source to the fully shielded position. • If this scenario does occur one should be able to pull hard on the controls to pull the exposure sheath out of its secured position and no component of the system should be damaged. • The operator should be able to return the source to the fully shielded position without exceeding the rotational force requirements of the system. • If one were to simulate this condition of securing the accessories, dropping the exposure device and then setting it so that the accessories do not release until a force of 1000N is applied I personally believe that would reduce the number of industry incidents and near miss situations by a considerable factor • The tests using 200N and 500N barely qualify as the weight of a falling device may exceed that quantity when you consider the free fall of the device + accessories.	
15	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 6.7.3.1 talks about simulating a “set up for use” scenario yet there is absolutely no mention of testing conditions with respect to different field conditions. • The exposure sheaths may pass this simple kinking test at 20 C, but the effects of temperature and the sun’s infrared emissions need to be taken into account. • If one were to take one of these currently certified black rubber guide tubes, situate it in Southern Alberta where the temperature hits 40 C during the day and let it sit in the direct sunlight for an hour you may find the surface temperature of the rubber to exceed 80 C • At these temperatures the rubber softens and it’s may be possible pull off the connectors with significantly less force than that of a standard test piece at 20 C inside a room without a radiant heat source • These guide tubes are however the best guide tubes for winter use so they should not be discounted. • I would suggest that the forces in the tests be increased dramatically and that	Section 2.3.1 of the guide requires that the designer demonstrate that the exposure device and its accessories can operate satisfactorily at the Canadian climate temperature range of - 40^{o} C to 45^{o} C.

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			they be performed at the two limits of temperature suggested by the manufacturer. • That is to say the rubber guide tubes may be tested from -40 C to +10 C and that specification will prohibit the use in a temperature that is below or above that specification.	
16		Chris Spencer Spencer Manufacturing (1983) Ltd.	ISO 3999:2004 section 6.7.4.1 talks about simulating the tensile stress during use, but 500N barely covers the force created from a free standing exposure device + controls. • The tests do not talk about testing in different field conditions (temperature + radiant energy from sunlight) • In order to reduce incidents the projection sheaths should be capable of withstanding any tensile force the operator may put onto the component. • In particular it should be able to withstand the force of an individual trying to pull the projection sheath out of a secure location during unexpected circumstances such as a shift in position of the exposure device during the cycle • It's possible that an operator without leverage could pull in excess of 1000N (I managed nearly 700N on dry concrete) • With leverage such as putting one foot on a pipe that value could easily double or triple. • One alternative would be to have all manufacturers design their exposure sheath/source stop assembly with a "break away" component that can be used for securing the assembly. • This way the exposure sheath can be secured and the exact quantity of force required to remove the assembly from the secure position is known. • If the manufacturer performs tensile tests up to 500N they would need to ensure that their break away system lets go at 75% of that value (375N) • With this type of "break away" built into the exposure sheath/source stop it could also potentially reduce the risk of kinking the accessories.	The test consists of simulating the tensile stress that may be experienced by the unit composed of the control assembly conduit, source assembly and exposure device during use. Proper use of the equipment would eliminate some of the concerns raised and are considered beyond the scope of this document. Further, the guide does not prevent the designer from incorporating the suggestions into the design. These suggestions could also be adopted by industry as good practice.

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17	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	Considerations: Manufacturing exposure devices is an expensive and risky venture, this is the reason there are so few manufacturers in the world. Canada is a relatively small market, with less than 1000 devices at an average retail of less than $15,000 representing $15 million in sales over a replacement cycle of 7-10 years. When a company is faced with spending several million on design/testing/certification/support there is a significant financial decision unless the device has a place in the global market. If a strong standard it put into place without 5-10 years of advanced notice it is possible that the manufacturing industry may collapse with all new design being excluded from the Canadian market. A phased introduction of stricter standards may allow manufactures the time to adapt, but other competent authorities and or the ISO group need to show an interest in implementing a standard which challenges the industry.	RD/GD-352, once published, will be used as guidance to assist applicants who want to apply for the certification of new exposure devices or accessories. The document will provide CNSC expectations with regards to the design requirements for exposure devices. The document is based on ISO 3999:2004, a standard used internationally for the design of exposure devices.
18	General	Chris Spencer Spencer Manufacturing (1983) Ltd.	Conclusion: I am limited in my time that I can spend on my response to this initial draft document; hopefully there will be time for further discussion with industry prior to implementation. There is more detail in the individual problems with ISO 3999:2004 but I wished to concentrate on stressing my opinion that that the current standards fail to simulate field conditions, they only serve as a very basic standard to satisfy various competent authorities and to limit the risk to the current manufacturers. Hopefully your group will set the bar a little higher than the current standards so that current manufacturers will be put in a position where they will need to come up with new innovative methods to achieve ALARA.	The CNSC would be happy to raise any issues or concerns that you may have to the ISO 3999 committee during the next review cycle. However, the current edition has been judged sufficient to ensure an acceptable level of safety.