

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

Peer Reviewers	Data Presentation – Accuracy, Completeness, Consistency	NIOSH Response
Comment 1	<p>I would encourage NIOSH to incorporate financial analysis into the process of selecting exposure control methods. A key assumption underlying control banding appears to be that a higher degree of control (e.g., containment, followed by engineering control) is generally expensive and therefore "overprotective" against exposure to substances in the lower risk categories. This assumption has driven the idea that control bands should be rigidly tied to specific risk levels. This assumption may be inaccurate in many cases and may complicate the control banding approach unnecessarily. In addition, for many substances there is less than complete information concerning their long-term human health effects, making R-phrases inadequate to fully describe the risk people in the workplace face if they are exposed. In such situations, a higher level of control would be prudent rather than overprotective.</p>	<p>NIOSH authors appreciate these comments, and have revised the document to address the key issues raised. Specifically, the following statement was added to the Executive Summary under research needs/ recommended activities for CB in the United States:</p> <p><i>Incorporate economic analyses into the process of selecting exposure control methods, with the goal of developing a more complete understanding of the relationship between the hierarchy of controls and their cost effectiveness.</i></p> <p>A more lengthy description of this recommendation was added under a later section of the document:</p> <p><i>Incorporate economic analyses into the process of selecting exposure control methods, with the goal of developing a more complete understanding of the relationship between the hierarchy of controls and their cost effectiveness. A key assumption underlying CB appears to be that a higher degree of control (e.g., containment, followed by engineering control) is generally expensive and may be "overprotective" against exposure to substances in the lower risk categories. This assumption has driven the idea that control bands should be rigidly tied to specific risk levels. This assumption may be inaccurate in many cases and may complicate the CB approach unnecessarily. In addition, for many substances there is less than complete information concerning their long-term human health effects, making R-phrases inadequate to fully describe the risk people in the workplace face if they are exposed. In such situations, a higher level of control would be prudent rather than overprotective.</i></p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 2</p>	<p>Throughout the document, the Health and Safety Executive is referred to as 'UK HSE'. HSE has jurisdiction in Great Britain (i.e. England, Scotland and Wales), but not Northern Ireland, so it should not be referred to as UK HSE. I suggest you use the term 'HSE in Great Britain' or just 'HSE'. The correct term is used on page 132, line 8 of this document.</p>	<p>NIOSH authors replaced "UK HSE" with "HSE" throughout the document.</p>
<p>Comment 3</p>	<p><u>Page 5: Origins of CB for chemical agents.</u> It would be helpful to comment "For example, occupational exposure limits act as 'control band' boundaries. OELs lie at 'preferred values' rather than scientifically precise values. They are not a hard and fast line between safe and unsafe. Like all control bands, there is a certain 'fragility' of scientific rigour at the boundaries."</p>	<p>NIOSH authors appreciate this comment and acknowledge the validity of the concept that control band boundaries are not a "hard and fast line;" most experts consider it to be a continuum. OELs can lie at the "mid-point" of the band rather than at the boundaries of the bands. NIOSH authors revised the document accordingly, adding text consistent with the suggested clarification.</p>
<p>Comment 4</p>	<p><u>Page 9, line 5</u> The COSHH regulations no longer have Maximum Exposure Limits (MELs) and Occupational Exposure Standards (OESs). Occupational exposure limits are called Workplace Exposure Limits (WELs).</p>	<p>NIOSH authors deleted MELs and OESs, added WELs, and included a comment consistent with the reviewer's clarification.</p>
<p>Comment 5</p>	<p><u>Page 9, line 10</u> In the current edition of the COSHH ACoP, the explanation of adequate control for substances without a WEL now refers to the principles of good practice and is located in paragraph 129.</p>	<p>NIOSH authors appreciate this clarification and added this comment and supporting reference.</p>
<p>Comment 6</p>	<p><u>Page 14, line 3</u> There is no 'maximum dust concentration' in the COSHH regulations. The level of 10 mg/m³ is a threshold of dust concentration. At or above this level, the dust (if not specified elsewhere) is defined as a substance hazardous to health and COSHH applies.</p>	<p>NIOSH authors revised the text, changing <i>maximum</i> to <i>threshold</i>, and revised wording further for clarification.</p>
<p>Comment 7</p>	<p><u>Page 26, Table 5</u> Add a note 'Note: COSHH essentials is regularly reviewed to reflect any changes to R-phrases'.</p>	<p>NIOSH authors incorporated the suggested revision at the end of the Table.</p>
<p>Comment 8</p>	<p><u>Page 80 lines 1-2</u> I suggest redraft: "Generic CB strategies such as COSHH essentials select control recommendations based on hazard and exposure ranges using general ventilation as a minimum; this system is not intended as a predictive exposure model." I think that Stoffenmanager is more clearly an exposure predictive system.</p>	<p>NIOSH authors appreciate this comment and revised the document accordingly to incorporate this clarification.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 9</p>	<p>Page 82, line 9 Suppliers don't quote dustiness, and rarely quote volatility (vapour pressure at a quoted temperature). They should quote boiling point for liquid substances and preparations. The user assesses dustiness subjectively, and we need better terms to discriminate low, medium and high dustiness.</p>	<p>NIOSH authors incorporated the suggested revision, adding two bullet points: "Suppliers should quote boiling point..." and "Establish better terms to discriminate low..."</p>
<p>Comment 10</p>	<p>Page 82, lines 12-13. Suggest redraft: "Construction of model to combine quantity in use, dustiness/volatility and other determinants, to predict the exposure band."</p>	<p>NIOSH authors incorporated the suggested revision.</p>
<p>Content and Conclusions – Additional Reference Suggestions; General or Specific Comments Regarding Text and Discussion</p>		
<p>Comment 11</p>	<p>A summary of the COSHH essential approach can be found in 'Risk management measures for chemicals: the "COSHH essentials" approach by A.N.I. Garrod, P.G. Evans and C.W. Davy. Journal of Exposure Science and Environmental Epidemiology (2007) 00, 1-7. The paper examines COSHH essentials as a suitable vehicle for communication risk management measures and would be an important reference for this review.</p>	<p>NIOSH authors reviewed and included reference to this manuscript in the revised document.</p>
<p>Comment 12</p>	<p>The Australian Safety and Compensation Council Department of Employment and Workplace Relations carried out a detailed evaluation of the use Printing essentials (DEWR research file WR07/12041 Occupational Health & Safety - Research - Development of Essential Chemical Controls for Australian Printers - 2007). Using the findings of the evaluation, a web-base package Essential Chemical Controls for Australian Printers has been developed. Contact - Howard Morris. The current system (with acknowledgements to HSE) is posted at: http://www.ascc.gov.au/ascc/HealthSafety/OHSstandards/EssentialChemicalControls/EssentialChemicalControlsforAustralia.nPrinters.htm</p>	<p>NIOSH authors appreciate the suggestion of this reference, but chose not to include it in the print version given its similarity to U.K. HSE products. NIOSH will consider adding this resource and any supporting documentation of the evaluation in updates to the Web version of the document given additional time to review and interpret these materials.</p>
<p>Comment 13</p>	<p>Page xvi, line 13 The term 'COSHH essentials' is a brand name; it is not an abbreviation for Control of Substances Hazardous the Health essentials. I suggest re-wording this section: 'COSHH essentials: A CB model developed by the British Health and Safety Executive (HSE) to assist small- and medium-sized enterprises in complying with Control of Substances Hazardous to Health (COSHH) Regulations. The</p>	<p>NIOSH authors revised the document to incorporate these suggested changes.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

Comment 13 (con't)	COSHH essentials guidance is available in both a published document and in a Web-based model known as eCOSHH essentials.	NIOSH authors added the word "Restriction" as suggested.
Comment 14	Page 3, line 7 The name of this regulation is the 'Registration, Evaluation, Authorisation and Restriction of Chemicals' (REACH).	NIOSH authors added "Institute of Chemical Engineers" as suggested (Table 1).
Comment 15	Page 7, Abbreviation Need to add 'ICE'	NIOSH authors incorporated the suggested revision.
Comment 16	Page 21 In the box, replace 'UK HSE' with 'Annals of Occupational Hygiene'.	NIOSH authors incorporated the suggested revision.
Comment 17	Page 23, line 10 I suggest adding 'welding' after 'woodworking' as it is mentioned earlier in that section (page 2, line 17).	NIOSH authors corrected the misspelled word as suggested.
Comment 18	Page 27, line 8 'dipropylene' is spelled incorrectly.	NIOSH authors incorporated the suggested revision.
Comment 19	Page 29, line 8 'engineering containment' should read 'engineering control'.	NIOSH authors incorporated the suggested revision.
Comment 20	Page 43, line 11 Inside the box, last sentence, I suggest adding 'process-generated hazards such as' before 'airborne crystalline silica'.	NIOSH authors incorporated the suggested revision.
Comment 21	Page 50, lines 3, 5 and 10 The bullets should be 1., 2., and 3. Not 4., 5., and 6.	NIOSH authors and editors revised and reformatted the document extensively to improve its organization and consistency.
Comment 22	Page 55, line 9 'tripartite' is spelled incorrectly.	NIOSH authors corrected the misspelled word as suggested.
Comment 23	Page 60, line 5 'Vickers' is spelled incorrectly.	NIOSH authors corrected the misspelled name as suggested.
Comment 24	Page 67-68 It would be very useful to include a statement such as "Control Banding schemes should inform Industrial Hygienists but not constrain their professional decisions."	NIOSH authors appreciate this comment and worked with editors to incorporate this statement into the revised document.
Comment 25	Page 78, lines 10, 11 The example in brackets needs rewriting to clarify the meaning.	NIOSH authors appreciate this comment and worked with editors to provide clarification for this statement in the revised document.
Comment 26	Page 78, line 22 Add 'to' after 'likely'.	NIOSH authors incorporated the suggested revision.
Comment 27	Page 80, line 17 Recommend replacing "likely" with "potential". Rarely are there sufficient data to be able to show log-normality.	NIOSH authors incorporated the suggested revision.

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

Comment 28	Page 80, line 22 The substances are corrosive, not irritant. Both are classified R35 (causes severe burns) by the EU.	NIOSH authors revised the text accordingly, changed it to state "corrosive, and classified R35(causes severe burns) by the EU."
Comment 30	Page 82, line 10 Add GHS H-statements.	NIOSH authors incorporated the suggested revision.
Comment 31	Page 94, line 16 Add Great Britain to the list of representatives.	NIOSH authors incorporated the suggested revision.
Comment 32	Page 111, line 9 Replace 'silica' with 'asbestos'.	NIOSH authors incorporated the suggested revision.
Comment 33	Page 112, line 9 Propose adding eg, 'and process-related emissions such as fume' before 'hazard control guidance'.	NIOSH authors incorporated the suggested revision.
Comment 34	Page 117, line 25 to 27 This should be a single reference 'HSE [2005]. Control of substances hazardous to health, Fifth Ed. The Control of Substances Hazardous to Health Regulations 2002 (as amended). Approved Code of Practice and Guidance. HSE Books, Sudbury UK. ISBN 0-7176-2981-3	NIOSH authors revised the document to cite the suggested reference in the References section.

Stakeholder Reviewers	Comment	NIOSH Response
Data Presentation – Accuracy, Completeness, Consistency		
Comment 35	1.6.7. Korea (KCT) Korean Control Toolkit (KCT) for chemicals has been developed by Korea Occupational Safety and Health Agency (KOSHA) in the Republic of Korea. KCT is a semi-quantitative assessment approach that provides advice on controlling the use of chemicals. Based on statistics of industrial accident compensation insurance, KCT will be available for 30 chemicals which have frequently caused occupational diseases in Korea for the last 15 years. And it has been developed in form of a web-based tool for SMEs. KCT takes account of real conditions such as, physicochemical properties and the amounts of the targeted chemicals, the duration and frequency of the work, the patterns of worker's exposure, and has utilized the algorithm used in COSHH Essentials of HSE to determine the grades of risk. KCT is focusing on process-	NIOSH authors appreciate the additional information provided, and used it to revise and update the Korea (KCT) section. NIOSH authors included a brief summary of the background of the system (based on the information and references provided by the reviewer) and instructions for using the tool kit.

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 35 (Con't)</p>	<p>specific controls for high risk processes which can cause occupational diseases in Korea. KOSHA has carried out the intensive nation-wide survey for 5 chemicals per year to find out real status of workplace using targeted chemicals in 2006-2010. The main information required to determine the risk level of the process has been gathered by the survey of KOSHA. Based on results of the survey, high risk processes have selected and the appropriate controls have been developed. These controls will be in accordance with KOSH Act and guidance and include standardized models with exposure scenarios for improvement of work environment, management of worker's health, administrative strategies, PPE selection and usage. Considering the situation of IH field like a poor private consulting system, KCT could be useful to assess the risk and to get information for the specified controls for SMEs without economic burdens. KCT will be consistently supplemented and adjusted by 2010.</p>	
<p>Comment 36</p>	<p>The ICCT is useful in assessing the health risk posed by airborne chemicals. The toolkit is a valuable supplemental risk assessment tool. However, there were various limitations associated with the tool. For example, non-health hazards associated with the chemicals are not taken into consideration. The applicability of the tool was also reliant on the availability of GHS classification and risk phrase data.</p>	<p>NIOSH authors appreciate this comment and agree with the reviewer. Some of the shortcomings of the ICCT are acknowledged in the document, while others are being addressed as additional evaluation and development of the tool continues.</p>
<p>Comment 37</p>	<p>The Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) must begin a process of updating the Hazard Communication Standard to incorporate elements of control banding as well as expected changes that will be brought about by GHS. This document will serve these agencies and the entire occupational safety and health community as efforts to move forward these issues forward. ...advancing these issues as quickly as is reasonably possible can only help our members' employers remain competitive in a rapidly changing international environment where control banding will play an increasingly important role in controlling workplace hazards.</p>	<p>NIOSH appreciates these comments supporting the utility and relevance of the document.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 38</p>	<p>Recommendations: 1) Update the document to include recently developed and implemented systems and to point out current directions. I include a number of detailed suggestions below. 2) The NIOSH Health Hazard Program is situated to carry out approaches based in control banding systems and to carry out comparisons with the traditional approaches used by HETAB. Some efforts of DART engineers also are suitable. This should be addressed within NIOSH and noted in this document. The introductory pages of the document describe in detail analyses focused on COSHH. Consider if any very recent analyses, for example of COSHH or Stoffenmanager, etc are needed. Consider if the new German and Dutch and Dutch efforts should be included? (E.g. Rolf Packoff and Henri Heussen). These pages do provide detailed thinking in the pros and cons sections, so may be ok...as long as the newer CB systems are added later in the document. There are two routes to the Silica Essentials guidance: Use http://www.coshh-essentials.org.uk/ > 2nd page, Option 4: Direct Advice > Production industries > Industry sector. Every task sheet leads to a download page for all advice sheets relating to that task. Use http://www.hse.gov.uk/pubns/guidance/index.htm for industry sector > task sheets. There is no simple route to the accompanying sheets for specific tasks.</p>	<p>NIOSH authors appreciate these comments and have incorporated these suggestions in citing specifically the studies by Jones and Nicas describing how NIOSH Health Hazard Evaluations compare to CB strategies and could possibly be better harmonized. Also, based on the comments from this and other reviewers with regard to COSHH Essentials, the document was substantially revised and updated such that the emphasis is not on the UK model as additional information about strategies and approaches (e.g., Stoffenmanager) has become available.</p>
<p>Comment 39</p>	<p>Use http://www.coshh-essentials.org.uk/ > 2nd page, Option 4: Direct Advice > Production industries > Industry sector. Every task sheet leads to a download page for all advice sheets relating to that task. Use http://www.hse.gov.uk/pubns/guidance/index.htm for industry sector > task sheets. There is no simple route to the accompanying sheets for specific tasks.</p>	<p>NIOSH authors appreciate this point of clarification, and have incorporated this suggestion by providing the address to the Silica Essentials through the HSE Web site by industry sector, using the bottom link.</p>
<p>Content and Conclusions – Additional Reference Suggestions; General or Specific Comments Regarding Text and Discussion</p>		
<p>Comment 40</p>	<p>Page xviii, line 9 Either expand the 5th itemized action to include safety specifically, or preferably, add a 6th item that expands on the need to address injury prevention and the addition of occupational safety in the CB process to address the need for multidisciplinary activities in the development of Toolbox approaches to achieve injury and illness prevention.</p>	<p>NIOSH authors appreciate the comment and have revised the document to address these comments and provide additional references supporting the application of CB approaches for ergonomic and other physical hazards.</p>
<p>Comment 41</p>	<p>Page xviii, line 6 Remove 'University of California' from David Zalk's affiliation. Deborah Nelson is now with 'University of Colorado, Boulder'.</p>	<p>NIOSH authors revised as suggested.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

Comment 42	Page 42, line 1 Include the ACGIH White Paper here, though it should be pointed out that, though it is titled 'CB', they are only evaluating COSHH Essentials and the ICCT and are evaluating CB as a whole since they did not evaluate all the other national approaches.	NIOSH authors appreciate this comment and have added reference to and discussion about the ACGIH White Paper on Control Banding.
Comment 43	Page 42, line 1 Perhaps this is a location for inclusion of the article by Zalk and Nelson (2008).	Discussion of the article by Zalk and Nelson (2008) was added to the document.
Comment 44	Page 47, line 8 Add weblink for RISKOFDERM	NIOSH authors added Web address to download RISKOFDERM Toolkit, version 1.1.
Comment 45	Page 47, line 19 Include NIOSH work in South America and discussions at regional workshops.	NIOSH authors have updated the document to provide description about the CB efforts to address silicosis in the Americas.
Comment 46	Page 48, line 2 Add weblink for Silica Essentials	NIOSH authors added a brief description and Web address for Silica Essentials.
Comment 47	Page 49, line 1 Update if MOU has already been signed	NIOSH authors confirmed that the MOU has not yet been formally signed.
Comment 48	Page 49, line 12, Box Add Korea and China (Get their Chemical Control systems and describe in document)	NIOSH authors added discussion of the Korean Chemical Toolkit as suggested, but could not find data or documentation describing a Chinese system.
Comment 49	Page 52 and following Add weblinks for each country CB system described on pp. 52-59. Add China and Korea systems here.	NIOSH authors added the following Web addresses for country specific CB approaches: <ul style="list-style-type: none"> • Regetox available in French or Dutch at https://www.regetox.be/accueil . • Dutch Stoffenmanager is available at https://www.stoffenmanager.nl/ • German GTZ's Chemical Management guide is available from their website http://www.gtz.de/en/ • Korean KOSHANET: Available in Korean Only. (Therefore could not find KCT directly) http://www.kosha.net/index.jsp • NIOSH authors could not find information on the Chinese system readily available in English.

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 50</p>	<p>Additional Remarks to Chapter 1.6 I. It may be useful to create a short new chapter "1.6.1 European Union" that gives a hint at the European Practical guidelines on Chemical agents directive 98/24/EC. In Annex II of the guidelines a CB scheme - quite similar to COSHH Essential - is recommended for risk assessment. The guidelines are addressed to the EU member states to be integrated into their national legislation, Codes of Practice or national Guidance documents, see: http://ec.europa.eu/employment_social/health_safety/docs/chemical_agent_en.pdf II. In its annual report 2006 the Finnish Institute of Occupational Health refers to the launch of a national CB tool for chemical risk management called SK2, see http://www.ttl.fi/Internet/English/Advisory+services/Occupational+Safety+Information+Systems.htm.</p>	<p>NIOSH authors appreciate these comments, but were unable to locate or review these resources sufficiently in time to incorporate reference to them in the document.</p>
<p>Comment 51</p>	<p>Page 52, after line 17 Please add the following paragraphs concerning implementation of CB in Germany: Since 2005 the German Federal Institute for Occupational Safety and Health (BAuA) offers an "Easy-to-use workplace control scheme for hazardous substances" (EMKG) as practical guidance for workplace risk assessment in small and medium enterprises [Arndt et al., 2005]. Using easy available informations from Safety Data Sheets and workplaces the user of the scheme can derive control strategies to minimise exposure via inhalation or skin contact. EMKG is quite similar to HSE's COSHH Essentials. The main differences are some divergent allocations of R-phrases to hazard bands following a similar Scheme for assessment of Substitutes [Geman FMLS, 2008] and a more detailed tool to assess dermal exposure [German FMLS, 2006]. Control guidance sheets for typical tasks give reference on precise control measures within the control strategy determined with the generic tool. In 2007 the generic control guidance sheets have supplemented with specific sheets for activities with chemicals in the rubber industry. Currently 36 control guidance sheets are offered on BAuA's web page with the same numbering than those from HSE (UK).</p>	<p>NIOSH authors appreciate this additional text and have utilized a revised version with the appropriate reference(s) in the document.</p>

Comment 51
(Con't)

From a legal point of view the EMKG is non-binding guidance. But it is, like COSHH Essentials, well supported by legal obligations and Codes of Practice from the tri-partite Hazardous Substances Committee in Germany. In general, German legal requirements for Occupational Safety and Health follow the minimum requirements for EU member states based on Art. 137 of the EU treaty [European Union 2003]. German Hazardous Substances Ordinance is the national implementation of the corresponding EU Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work [European Union, 1998]. The Code of Practice TRGS 400 „Risk Assessment for Chemicals at the Workplace“ specifies the EMKG as an easy available information for employers to carry out workplace risk assessments [German FMLS, 2008]. The control guidance sheets are accepted by the Competent Authorities in the federal states of Germany as a procedure to improve compliance with the Hazardous Substances Ordinance for substances without an OEL [German FS 2005].

Beyond this two branch-specific control banding tools in Germany should be noted: GISBAU - a well-established hazardous substances information system of the institutions for statutory accident insurance and prevention in the building trade [GISBAU, 1989], and the building blocks for workplace risk assessment of the Institution for Statutory Accident Insurance and Prevention in the Health and Welfare Service [BGW, 2006].

In May 2008 an enhanced version of the scheme (EMKG 2.0) has been launched on the BAuA website [Kahl et al., 2008]. EMKG 2.0 additionally includes now all 300 substances with a legal OEL in Germany. For these substances the user of the

<p>Comment 51 (Con't)</p>	<p>scheme does not start with the classification but with the OEL, which is addressed to a corresponding hazard band. Keeping in mind the uncertainties of the scheme, two possibilities for practical implementation are offered. The first is to use the hazard group which directly relates to the target airborne concentration range which covers the OEL. In this case the employer has to improve the observance of the OEL by applying workplace measurements. The second possibility is to use the hazard band below the OEL and the corresponding control strategy. In these cases the employer can waive workplace measurements.</p> <p>The expansion of EMKG 2.0 to substances with an OEL makes it compatible to future demands. EMKG can be used as a simple tool to derive exposure scenarios for substances to be registered under the EU REACH regulation by using the DNEL (derived no effect level), which is the REACH surrogate for an OEL. A more specific EMKG-based online-tool is under current development at BAuA to help producers and importers of chemicals to fulfill the REACH requirement to derive control strategies and to recommend management measures, e. g. the corresponding guidance sheets.</p> <p>[Arndt, 2005] Arndt, Rainer; Packroff, Rolf; Görner, Bettina; Guhe, Christine; Lechtenberg-Auffarth, Eva; Lotz, Gabriele; Tischer, Martin: Einfaches Maßnahmenkonzept Gefahrstoffe: Eine Handlungshilfe für die Anwendung der Gefahrstoffverordnung in Klein- und Mittelbetrieben bei Tätigkeiten mit Gefahrstoffen ohne Grenzwert, Gefahrstoffe - Reinhaltung der Luft, 65 (2005) No. 1-2, p. 13-18 (in German, English Version of EMKG 1.0 see www.baua.de/nr_18306/en/Topics-from-A-to-Z/-Hazardous-Substances/workplace-control-scheme.pdf).</p>	
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<p>Comment 51 (Con't)</p>	<p>[German FMLS, 2008] Federal Ministry for Labour and Social Affairs, Code of Practice TRGS 600 "Substitution", to be published (in German)</p> <p>[German FMLS, 2006] Federal Ministry for Labour and Social Affairs, Code of Practice TRGS 401 "Dermals risk from chemicals - characterisation, assessment, management", Bundesarbeitsblatt 10 (2006) see www.baua.de/de/Themen-von-A-Z/-Gefahrstoffe/TRGS/TRGS-401.html nnn=true (in German)</p> <p>[European Union, 2003] Treaty establishing the European Communities (as amended by the Amsterdam Treaty), Article 137 http://ec.europa.eu/employment_social/egu_opp/treaty_en.htm#137</p> <p>[European Union, 1998] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), Official journal No. L 131, 05/05/98 p. 11 -23, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0024:EN:HTML</p> <p>[German FMLS, 2008] Federal Ministry for Labour and Social Affairs, Code of Practice TRGS 400 „Workplace Risk Assessment for workplace use of chemicals“, Gemeinsames Ministerialblatt der Bundesministerien, 11/12(2008), p. 211 - 223, see www.baua.de/de/Themen-von-A-Z/-Gefahrstoffe/TRGS/TRGS-400.html nnn=true (in German)</p> <p>[German FS, 2005] German Federal states instruction for implementation of OSH legislation: "Guidelines on hazardous substances ordinance (LV 45, 2005)", see</p>
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NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 51 (Con't)</p>	<p>http://lasi.osha.de/de/gfx/publications/lasi_publications.php (in German)</p> <p>[GISBAU, 1989] GISBAU - the hazardous substances information system of the institutions for statutory accident insurance and prevention in the building trade, see osha.europa.eu/good_practice/sector/-construction/construction_case_studies_2.pdf</p> <p>[BGW, 2006] BGW (Institution for Statutory Accident Insurance and Prevention in the Health and Welfare Service): building blocks for workplace risk assessment (2006), http://www.bgw-online.de/internet/generator/Navibgw-online/NavigationLinks/Kundenzentrum/Grundlagen_und_Forschung/Gefahrstoffe/Bausteine_zur_Gefaehrdungsbeurteilung/navi.html</p> <p>[Kahl et al., 2008] Kahl, A; Johnen, A.; Guhe, C.; Packroff, R.; Lotz, G., Tischer, M., Einfaches Maßnahmenkonzept Gefahrstoffe, Version 2.0 (2008), see www.einfaches-manahmenkonzept-gefahrstoffe.de (in German)</p>	<p>NIOSH authors have updated the document with additional discussion about the German (BauA), GTZ, and other country- specific CB systems. Also, the JOEH reference by Zalk and Nelson (2008) has been added with discussion.</p> <p>NIOSH authors appreciate this comment and have revised the document to include the appropriate Web address provided.</p> <p>NIOSH authors have included information describing both the German and Dutch systems.</p> <p>NIOSH authors appreciate this comment, and have completely revised this section based on the clarification and references provided by the reviewer.</p> <p>NIOSH authors have updated the document with additional discussion about Dutch Stoffenmanager. Also, the JOEH reference by Zalk and Nelson (2008) has been added with discussion.</p>
<p>Comment 52</p>	<p>Page 53, line 17 Germany now has its own online CB toolkit approach that is separate and distinct from the GTZ work. It is from BAuA, can be seen as comparable to COSHH or Stoffenmanager, and is expounded within the Item JOEH reference below.</p>	<p>NIOSH authors have updated the document with additional discussion about the German (BauA), GTZ, and other country- specific CB systems. Also, the JOEH reference by Zalk and Nelson (2008) has been added with discussion.</p>
<p>Comment 53</p>	<p>Page 54, line 11 The link to the GTZ Chemical Safety Management project is: http://www.gtz.de/en/themen/laendliche-entwicklung/7720.htm</p>	<p>NIOSH authors appreciate this comment and have revised the document to include the appropriate Web address provided.</p>
<p>Comment 54</p>	<p>Page 54 Add new German and Dutch systems.</p>	<p>NIOSH authors have included information describing both the German and Dutch systems.</p>
<p>Comment 55</p>	<p>Page 55, lines 7 – 13 Delete these lines in lieu of revisions above noted for Page 52, after Line 17.</p>	<p>NIOSH authors appreciate this comment, and have completely revised this section based on the clarification and references provided by the reviewer.</p>
<p>Comment 56</p>	<p>Page 55, line 14 Include current discussion of Stoffenmanager, drawing from description in Zalk and Nelson (2008).</p>	<p>NIOSH authors have updated the document with additional discussion about Dutch Stoffenmanager. Also, the JOEH reference by Zalk and Nelson (2008) has been added with discussion.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

Comment 57	<u>Page 56</u> Add new Stoffenmanager CB Construction system	NIOSH authors have included information about the Dutch Stoffenmanager system.
Comment 58	<u>Page 57</u> Add SOBANE Belgium system	NIOSH authors have included information about the SOBANE system.
Comment 59	Please consider notes concerning a method that has been developed in Belgium and that is used successfully in many small ans large companies to organise prevention programs concerning the chemical agents. This might complete the information given in the draft report on CB about what has been done in Belgium. This SOBANE strategy refers actually to the control banding documents.	NIOSH authors appreciate this information and comments, and have incorporated revisions and additional details provided into the document.
Comment 60	<u>Page 58</u> Check that Singapore description is up to date	NIOSH authors updated the description of the Singapore system (SQRA) based on comments from the reviewer from the Singapore Ministry of Manpower and information from a reference by Zalk and Nelson (2008).
Comment 61	<u>Page 59</u> Add 1.6.7 Korea and 1.6.8 China	NIOSH authors included reference to the Korean program as suggested in reformatted sections of the revised document. NIOSH authors could not find information on the Chinese system readily available in English.
Comment 62	<u>Page 59, line 17</u> There is now work with model variations in India, Japan, South Korea, and more.	NIOSH authors have updated the document with additional discussion about country-specific and activities relating to further development, application, and evaluation of CB available at the time of publication.
Comment 63	<u>Page 60, line 1</u> Change 'Recent' to 'Special' as 2002 is not recent.	NIOSH authors revised as suggested.
Comment 64	<u>Page 60, line 2</u> Spell out First International Control Banding Workshop (ICBW)	NIOSH authors revised as suggested.
Comment 65	<u>Page 60, line 5</u> Correct spelling for Vickers.	NIOSH authors revised as suggested.
Comment 66	<u>Page 63, line 17 and Appendix C</u> Check that the ITG version is current. Add weblink.	NIOSH authors confirmed that the version included was current. A second 5-year plan was under development and finalization at the time this document was going to press.
Comment 67	<u>Page 63, lines 19 and following</u> Please include ICBW3, September 2005 in Pilaesberg, South Africa, Third International Control Banding Workshop (ICBW3).	NIOSH authors appreciate this comment and have added a version of the descriptive text provided as suggested.

Comment 67
(Con't)

The Third International Control Banding Workshop [ICBW3] was held 21 September 2005 at the Pilianesberg National Park in South Africa in conjunction with the 6th International Scientific Conference of Occupational Hygiene (IOHA 2005). Probably the most important part of the unique nature of ICBW3 was its location, occurring for the first time outside the developed nations and solidifying the inextricable involvement of developing countries. This offered a unique perspective for presenting the ongoing process to discuss, evaluate, and further the concept of Control Banding. The three focus topics for ICBW3 included the following sessions: Global Trends in Control Banding Collaborations, a Silica Workshop, and Control Banding's Expansion of Range beyond chemicals. The last two sessions highlighted the future context of the ICBWs, to further develop specific professional areas of practical prevention needs. The second session focused on silica and how Control Banding concepts could assist in accomplishing objectives on the ILO and WHO efforts relating to the International Programme on the Elimination of Silicosis. The discussions included the need for attention to worker health surveillance programs and examples of how an international silica toolkit could be utilized to start similar exposure reduction program in the countries now that the radiograph process had been completed. The closing session an eye on the future with details toward the expansion in the range of Control Banding strategies beyond the chemical realm. This included the expansion of ergonomic toolkit efforts that were initially presented at ICBW2 and had grown to include the International Ergonomics Association (IEA) participation with its NGO role in the WHOCC working in a parallel manner to early IOHA efforts (Zalk 2003). The theoretical future context for the expansion into the greater OSHH professions included psychosocial and safety considerations, and the opportunity to utilize video exposure modeling in Control Banding applications that are examples of what is essential to create a truly holistic primary prevention process for major illness and injury issues internationally. Taken together, the vision of combining the growing variety of OSHH toolkits parameters toward the needs of major trades was presented in the form of a Construction Toolbox built

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 61 (Con't)</p>	<p>upon the successes of the recent past. Discussions that were integral to ICBW3 included a call for the scaling of "basic" risk reduction tools to those with and without funds. It was agreed that associated costs for achieving this are not in the development but in the implementation. To ensure that the obligation for this implementation is shared, international experts and government entities require a system to offer continuity over time. Therefore, included in the future vision are practical elements to promote small loans for enterprises and create funding mechanisms for implementation, validation, and maintenance over time.</p> <p>NOTE: In addition, ICBW4 will be held in Seoul, South Korea at the XVIII World Congress on Safety and Health at Work on 1 July 2008. It will have an emphasis on safety and exploration into the latest national programs (India, South Korea, and Japan) and include IEA's including themselves in the ongoing CB effort with their latest Checkpoints. Marilyn is the keynote.</p>	
<p>Comment 68</p>	<p>Construction Toolbox</p> <p>Control Banding (CB) strategies offer simplified solutions for controlling worker exposures to constituents often encountered in the workplace. The expansion of CB models, or toolkits, within the greater occupational health and safety professions affords an opportunity to seek prevention of work-related illnesses and injuries affecting the world's 2.8 billion workers. Multidisciplinary CB models for work-related risk reduction in construction need to unite the variety of hazards (chemical, ergonomic, safety, and environmental) faced by the industry's workers. Thus, the incorporation of individual toolkits into a Construction Toolbox is an appropriate next step. The International Control Banding Workshops have facilitated toolkit approaches for ergonomics, silica, and safety in a manner that includes the provision of national-level guidance and coordination of pilot projects at the state level. This Occupational Risk Management Toolbox approach concept has become a by-product of this coordination, which has broadened the CB model to include a more comprehensive exposure control basis for universal industries</p>	<p>NIOSH authors appreciate this additional text and have utilized a revised version with the appropriate reference(s) in the document.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 68 (con't)</p>	<p>such as construction and agriculture. Working to further develop this multidisciplinary effort is an international, informal working group that includes the U.S., U.K., and The Netherlands that is seeking occupational health and safety professional input toward the development of a task-specific Construction Toolbox framework.</p> <p>Zalk, DM. Barrier Banding and the Construction Toolbox. Proceedings of 4th International Control Banding Workshop at XVIII World Congress on Safety and Health at Work. Seoul, South Korea (2008).</p> <p>Thienen, G, van, Spee, T. Health Effects of construction materials and construction products. J App Occup Sci. 1 (2008) http://www.ohici.nl/pdf/health_effects_of_construction_materials.pdf</p>	
<p>Comment 69</p>	<p><u>Pages 65-82</u> Update this section BEYOND COSHH. Add critiques at least of Stoffenmanager.</p>	<p>NIOSH authors have revised this section to include additional critiques of CB models.</p>
<p>Comment 70</p>	<p><u>Page 66, Table 16</u> Missing from Table are some key issues, such as</p> <ul style="list-style-type: none"> • Usefulness to users • Effectiveness of controls • Impact on workplaces • Cost effectiveness for employers • Cost effectiveness to society 	<p>NIOSH authors appreciate this comment, but found these additional issues to be beyond the scope of the table or lacking data for documentation. The table was revised for clarity, but not substantially changed.</p>
<p>Comment 71</p>	<p><u>Pages 83-88, Section 2.2.</u> Review to make any needed changes to include systems added in Section 2.1.</p>	<p>NIOSH authors worked with editors to reorganize, clarify and provide updates based on comments received from reviewers and recently-published literature.</p>
<p>Comment 72</p>	<p><u>Page 89, Section 2.3</u> Also review to make any needed changes to include systems added in Section 2.1.</p>	<p>NIOSH authors worked with editors to reorganize, clarify and provide updates based on comments received from reviewers and recently-published literature.</p>
<p>Comment 73</p>	<p><u>Page 91, line 6</u> Add Stoffenmanager Construction.</p>	<p>NIOSH authors revised as suggested to include reference to Dutch Stoffenmanager.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 74</p>	<p>Page 91, line 16 and following As the IEA has now adopted the CB approach (see ICBW4 discussion), perhaps this should be acknowledged within this section.</p>	<p>NIOSH authors appreciate this comment and have included discussion of the ICBW4 and reference to the IEA application of CB.</p>
<p>Comment 75</p>	<p>Page 91, Section 2.3.1.2.2 Add Zalk Ergonomics.</p>	<p>NIOSH authors revised as suggested to include reference to ergonomics applications in citation by David Zalk.</p>
<p>Comment 76</p>	<p>Page 91, Section 2.3.1.2.3 Add Stavroula Leka Psychosocial Risk Management Toolkit (PRIMAT) The development of the Psychosocial Risk Management toolkit has started with the definition of key principles and a framework of best practice for psychosocial risk management. As part of the framework guidelines on risk assessment, risk reduction interventions and evaluation of interventions will be developed for organisations. The framework also considers key indicators and aspects of corporate social responsibility, identification of key stakeholders, cost effectiveness and societal learning. It goes a step further to consider the policy levels and its link to practice, both at the enterprise level and the national context. The next steps of the project will include the development of toolkits for the enterprise and the national levels as well as training materials. More information on progress achieved so far may be found at: www.prima-ef.org Publications, fact sheets and guidance will become available from October 2008. For any additional information, please contact Stavroula.Leka@nottingham.ac.uk</p>	<p>NIOSH authors appreciate this comment and revised the text to incorporate the description of PRIMAT provided.</p>
<p>Comment 77</p>	<p>Page 91, Section 2.3.1.2.4 Add Susan Wilburn/Maria Lioce-Mata Healthcare Workers Toolkit.</p>	<p>NIOSH authors appreciate this comment and added text to reference the Healthcare Workers Toolkit as suggested.</p>
<p>Comment 78</p>	<p>Page 92, line 8 and following Safety expansion has already begun and is being furthered in the Netherlands. There are three topics in this section that should be separated: Safety, Environmental, and Construction Toolbox. Only Environmental has not yet been addressed specifically. Safety and Construction Toolbox discussions can re-emphasize the ongoing work (items 3 – 4) and develop a US approach for joining in on Safety as NIOSH is already part of the International Working Group on the Construction Toolbox (Lentz and Gillen).</p>	<p>NIOSH authors appreciate these comments, but chose not to describe these details as they are in the preliminary and exploratory stages and lack documentation.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

Comment 79	<p>Page 92, line 19 Add 'and other countries' after 'for implementation in the U.S'. Are there examples for which weblinks could be provided.</p>	NIOSH authors revised as suggested.
Comment 80	<p>Page 93, line 17 Insert after 'winning' the words 'and regional partnering'</p>	NIOSH authors revised as suggested.
Comment 81	<p>Page 94, line 1 Spell out Occupational Risk Management (ORM) Toolbox</p>	NIOSH authors revised as suggested.
Comment 82	<p>Page 95, line 5 Delete sentence beginning 'Such efforts...' Replace with the following: Such efforts would be consistent with the activities of the World Health Organization Network of Collaborating Centers in their 2006-2010 Work Plan, which includes 25 risk management (CB) projects. www.who.int/occupational_health</p>	NIOSH authors revised as suggested.
Comment 83	<p>Page 95, line 13 REACH has driven CB development within national OHSMSs, perhaps the US needs a similar driver. A discussion on these lines would be great to see. In fact, a separate REACH section would be wonderful as this is the driver that created online toolkits in the Netherlands and Germany, with more to come.</p>	NIOSH authors appreciate this comment, but feel that discussion of such a topic lacks documentation and is beyond the scope of the document.
Comment 84	<p>Page 95, line 14 Need reference...to what does this apply? Is it correct?</p>	NIOSH authors were unable to identify the specific location of the issue raised, but checked the section to verify that statements were appropriately referenced and accurate.
Comment 85	<p>Page 95, line 15 Insert description and references and weblinks for GTZ/India partnering on tanneries.</p>	NIOSH authors appreciate this suggestion, but found documentation and Web addresses lacking and consequently could not provide this information.
Comment 86	<p>Page 95, lines 16-33 Make this a paragraph to follow after the tannery example</p>	NIOSH authors worked with editors to reorganize, clarify, and reformat this and other sections of the document.
Comment 87	<p>Page 95, line 24 Insert a new section 2.3.2.1.2 (and renumber subsequent sections) on Regional Partnering of Countries. Insert the Americas Silica Control Banding effort</p>	NIOSH authors appreciate this comment and revised the document to provide additional description of the Americas Silica Control Banding efforts.
Comment 88	<p>Page 95, line 25 Insert 'or sectors' after 'large scale industries'</p>	NIOSH authors revised as suggested.
Comment 89	<p>Page 101, Section 2.5. Add Nanotechnology Section. Update as needed. 2.5.1 Ergonomics e.g. line 15. Do the same for Noise and Injury</p>	NIOSH authors appreciate this comment and revised the document to provide additional description about Nanotechnology applications.

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 89 (Con't)</p>	<p>(Barrier Banding)</p>	<p>Regarding the statement following Ergonomics, NIOSH authors do not agree with the reviewer that Barrier Banding has been sufficiently applied and documented to make statements about its utility for addressing other physical hazards. The authors did include description and reference to the citation by Swuste and Zalk (in press) describing Barrier Banding.</p>
<p>Comment 90</p>	<p>Nanotool: Qualitative risk assessment leading to controls for nanomaterial work. ABSTRACT: Control Banding (CB) strategies offer simplified solutions for controlling worker exposures to constituents that are found in the workplace in the absence of firm toxicological and exposure data. These strategies may be particularly useful in nanotechnology applications, considering the overwhelming level of uncertainty over what nanomaterials and nanotechnologies present as potential work-related health risks, what about these materials might lead to adverse toxicological activity, how risk related to these might be assessed, and how to manage these issues in the absence of this information. This study introduces a pilot CB tool or 'CB Nanotool' that was developed specifically for characterizing the health aspects of working with engineered nanoparticles and determining the level of risk and associated controls for five ongoing nanotechnology-related operations being conducted at two Department of Energy (DOE) research laboratories. Based on the application of the CB Nanotool, four of the five operations evaluated in this study were found to have implemented controls consistent with what was recommended by the CB Nanotool, with one operation even exceeding the required controls for that activity. The one remaining operation was determined to require an upgrade in controls. By developing this dynamic CB Nanotool within the realm of the scientific information available, this application of CB appears to be a useful approach for assessing the risk of nanomaterial operations, providing recommendations for appropriate engineering controls, and facilitating the allocation of resources to the activities that most need them.</p>	<p>NIOSH authors appreciate this additional text and have incorporated a revised version with the appropriate reference in the document.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 90 (Con't)</p>	<p>Paik, S, Zalk, DM, Swuste, P (2008). Application of a pilot control banding tool for risk level assessment and control of nanoparticle exposures. Accepted 28 May 2008 by Ann. Occ. Hyg.</p>	
<p>Comment 91</p>	<p>Barrier Banding: Development of an injury prevention toolkit. Similar to the banding of chemicals by toxicity, classifications already exist for various variables of accident causation. Banding safety risks for selection of appropriate barriers for injury prevention is similar to selecting appropriate engineering controls based on chemical hazard bands in CB. Barriers to injury, including management factors, are strongly related to the quality of safety management systems, and are important parameters for risk prevention. Presented for your consideration, this Barrier Banding model would apply safety phrases to accident scenarios or related situations and guide the user to the type of precautions needed to work toward an injury prevention toolkit. Swuste, P, Zalk, DM. 'Control banding' or 'barrier banding,' a qualitative tool for risk prevention. Am J Ind Med. In press (2008). Swuste, P. Qualitative Methods for Occupational Risk Prevention Strategies in Safety, or Control Banding Safety. Saf Sci Mon. 3(11) (2007) http://www.monash.edu.au/muarc/jps/vol11/Issue3/index.htm</p>	<p>NIOSH authors appreciate this additional text and have utilized a revised version with the appropriate reference(s) in the document.</p>
<p>Comment 92</p>	<p>Zalk, DM. Practical prevention in safety: from control banding to barrier banding. In International Working on Safety Conference. 2006. Eemhof, The Netherlands (2006). Page 104, lines 13-15</p>	<p>NIOSH authors revised as suggested.</p>
<p>Comment 93</p>	<p>Correction. Change to say 'The concept is currently housed within the WHO Collaborating Centers (WHOCC) Network Work Plan 2006-2010. http://www.who.int/occupational_health Page 104, line 16 Change 70 to 65</p>	<p>NIOSH authors revised as suggested.</p>
<p>Comment 94</p>	<p>Page 105, line 2 Spell out International Technical Group (ITG)</p>	<p>NIOSH authors revised as suggested.</p>
<p>Comment 95</p>	<p>Page 105, line 4 Delete 'recently'.</p>	<p>NIOSH authors revised as suggested.</p>

NIOSH Responses to Peer reviewers' comments and Stakeholders' submissions

<p>Comment 96</p>	<p>Page 108, line 3 Add a sentence: 'Sharing of information about effectiveness of the controls, cost-effectiveness of the controls, user-friendliness of the guidance, and impact on workplaces and society should be facilitated.'</p>	<p>NIOSH authors appreciate this comment, but do not feel it is an objective statement to be included.</p>
<p>Comment 97</p>	<p>Page 109, line 5 This sentence is not clear..what is 2005 NCBW and what is meant by the sentence?</p>	<p>NIOSH authors have included discussion in the document describing the National Control Banding Workshop (2005 NCBW) and its proceedings.</p>
<p>Comment 98</p>	<p>Page 111, Section 4.1.3 Add</p> <ul style="list-style-type: none"> • 1. Convert existing guides and solutions documents to 'toolkits' by beginning the document with instructions how to do a qualitative risk assessment of the workplace. • 5. Develop sector specific toolkits, for example Health Care Workers and Construction. 	<p>NIOSH authors revised as suggested.</p>
<p>Comment 99</p>	<p>Page 112, line 4 START AT HOME!!!! Insert at beginning of the second sentence 'The NIOSH Health Hazard Evaluation Program and ...continue with...the State OSHA..etc'</p>	<p>NIOSH authors appreciate the comment, but do not agree with the concept that Control Banding as currently recognized is a practice which NIOSH has historically acknowledged or utilized. No change made.</p>
<p>Comment 100</p>	<p>Page 131, Appendix C Be sure this is the current ITG version.</p>	<p>NIOSH authors confirmed that this is the initial implementation strategy developed by the ITG, and the second 5-year plan was in development and revision at the time this document went to press.</p>